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Instructions for Use – US

Callisto™



Interacoustics

D-0101246-L – 2020/01

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1. Introduction

1.1 About this manual

This manual is valid for the Callisto™. The product is manufactured by:

Interacoustics A/S
Audiometer Allé 1
5500 Middelfart
Denmark
Tel.: +45 6371 3555
Fax: +45 6371 3522
E-mail: info@interacoustics.com
Web: www.interacoustics.com

1.2 Intended use

The Callisto™ is intended for determination of hearing threshold levels and for verifying hearing aid performance in the fitting situation.

Intended Operator

The Callisto™ is intended to be operated by an Audiologist, ENT professional or a person with equivalent knowledge. Using the instrument without adequate knowledge may lead to erroneous results and may endanger the patients hearing

Intended Patient Population

This instrument is intended for all patient groups regarding sex, age and health. For audiology examinations the patient must be able to respond to the test signal in a rational way.

Contraindications

None known.

1.3 Product description

The Callisto™ is a Hearing Aid Analyzer that interfaces with integrated audiologic software modules on a PC. Depending on the installed software modules they can perform:

- Audiometry (AC440)
- Real Ear Measurements (REM440) including Visible Speech Mapping
- Hearing Instrument Testing (HIT)

1.4 Included and optional parts and accessories

Standard Parts for the Callisto™ Unit:

- Callisto™ Unit
- Callisto™ Suite Installation USB Drive, incl. Instructions for use and Quick Guides.
- Callisto Carrying Bag
- Callisto Foam Insert (standard bag)
- Standard USB Cable (2m)

Mouse Pad**Optional Parts for the Callisto™ Unit**

- Wheeled Carrying Case
- Callisto™ Foam Insert (optional bag with wheels)

AC440	REM440	HIT440

AC440 Standard Parts
• DD45[1] or TDH39[1] Audiometric Headset
• MTH400m Monitor Headset
• B71[2] Bone Conductor
• APS3 [1]Patient response button
 	
AC440 Optional Parts
• TDH39[1] Audiometric Headset
• HDA300[1] Audiometric Headset 30° plugs
• Eartone 3A Insert earphones[2)]
• Eartone 5A Insert earphones[2)]
• IP30[1] Insert earphones
• B71[2] Bone Conductor
• B81[1] Bone Conductor
• EMS400[1] Talk Back Microphone
• SP70 Loudspeaker + wire
• SP85A Loudspeaker
• SP90A Loudspeaker
• OtoAccess® Database
• Accessory bracket
 	
Special Tests:
Optional special tests:
• High Frequency audiometry (HF440)
• Multi Frequency module (MF440)
• Speech from hard-drive (SFH440)
• SISI test
• Master Hearing Aid (MHA440),
• Hearing Loss Simulator (HLS440)
• QuickSIN
• TEN test
	REM440 Standard Parts
	• IHM60 In-situ Headset (kit)
	• Probe Tubes 36 pcs
	• Edifier Loudspeaker + Wire
	
	REM440 Optional Parts
	• Extra Edifier Loudspeaker + Wire
	• Callisto™ Coupler Base Kit which includes:
	  ○ Coupler Base
	  ○ Coupler Box
	  ○ Reference Microphone
	  ○ 2cc Coupler
	  ○ ½” Microphone
	  ○ BTE Adaptor with O
	  ○ ITE Adaptor with O
	  ○ Body Adaptor with O
	  ○ BTE Tubing 27mm for BTE adaptor
	  ○ SPL60 In-situ Probe Tip-set + Coupler Adaptor
	  ○ Coupler Seal Wax
	  ○ OtoAccess® Database
	  ○ Accessory bracket
		HIT440 Standard Parts:
		• TBS10 Test Box
		• 2cc coupler with microphone and adaptors for ITE, BTE and Body Style HA
		• Coupler seal wax
		• Reference microphone
		
		HIT 440 Optional parts:
		• Couplers 1.2CC and 0.6CC: ITE, BTE, Ear simulator
		• Calibration adaptor
		• OtoAccess® Database

1) Applied part as according to IEC60601-1

2) This part is not certified according to IEC 60601-1.

1.5 Warnings and precautions



Throughout this manual the following meaning of warnings, cautions and notices are used:



WARNING

The **WARNING** label identifies conditions or practices that may present danger to the patient and/or user.



CAUTION

The **CAUTION** label identifies conditions or practices that could result in damage to the equipment.

NOTICE

NOTICE is used to address practices not related to personal injury.



When connecting this device to a computer it is essential to insert a galvanic separation between the device and the computer, unless the computer is battery operated or supplied by a medical approved power supply. If connecting directly to a PC it must be supplied from a medical isolation transformer fulfilling the requirements of IEC/ES 60601-1.

Please note that if connection is made to standard equipment like an active speaker, special precautions must be taken in order to maintain medical safety. If used without galvanic separation, it must be supplied from a medical isolation transformer fulfilling the requirements of IEC/ES 60601-1.

Do not touch the patient while operating PC, printer etc.

No modification of this equipment is allowed without Interacoustics authorization.
Interacoustics will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of this.

No part of the equipment can be serviced or maintained while in use with the patient.



Although the instrument fulfils the relevant EMC requirements precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears, e.g. unwanted noise in headphones. If disturbances are observed, try to separate the Callisto from the disturbing device. Please refer to the section for Electromagnetic Compatibility (EMC).

Do not disassemble or modify the product as this may impact the safety and/or performance of the device.

The internal battery shall be replaced by authorized personnel.

When using insert ear phones, make sure that foam or ear-tip is mounted correctly.

It is recommended that the disposable foam ear-tips supplied with the optional IP30, E.A.R Tone 3A or E.A.R Tone 5A insert transducers are replaced after each client tested. Disposable plugs also insure that sanitary conditions exist for each of your clients.

It is recommended that parts which are in direct contact with the patient (e.g. earphone cushions) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.

The transducers (headphones, bone conductor, etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers requires a new calibration.

Interacoustics will not make any guarantee to the functionality of the system if any other software is installed, with exception of the Interacoustics measurement (AC440/REM440) modules and AuditBase system4, OtoAccess® or a Noahcompatible Office Systems or later releases.

NOTICE

If this apparatus is connected to one or more other devices with medical CE marking, to make up a system or pack, the CE marking is only valid also for the combination if the supplier has issued a declaration stating that the requirements in the Medical Device Directive article 12 are fulfilled for the combination.

The instrument is intended for continued use. However, there is a risk of damaging the transducers if they are operated at the highest intensities for longer periods.
The transducers (headphones etc.) supplied with the instrument are calibrated to this instrument - exchange of transducers requires a new calibration.

No installation precautions are necessary to avoid unwanted sound radiation from the audiometer.

There is no warm-up time for the instrument but allow it to become acclimatised before use.

Be sure to use only stimulation intensities, which will be acceptable for the patient.
The reference and the probe microphones can be verified using the procedures described in calibration software.



Within the European Union it is illegal to dispose of electrical and electronic waste as unsorted municipal waste. Electrical and electronic waste may contain hazardous substances and therefore have to be disposed of separately. Such products will be marked with the crossed-out wheelie-bin image shown to the left. User cooperation is important in order to ensure a high level of reuse and recycling of electrical and electronic waste. Failure to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

Only recorded speech material with a stated relationship with the calibration signal should be used. In the calibration of the instrument it is assumed that the calibration signal level is equal to the average level for the speech material. If this is not the case, the calibration of the sound pressure levels will be invalid and the instrument needs recalibration.

To establish conformity with the IEC 60645-2 standard, it is important that the speech input level is adjusted to 0VU. It is equally important that any free field installation is calibrated at the site where it is used and under the conditions that exists during normal operation.

Great care should be exercised by the handling of earphones and other transducers, as mechanical shock may cause change of calibration.

The specification for the instrument is valid if the instrument is operated within the environmental limits specified in technical specifications. Supply voltage: USB-powered (USB Type B connector).

To prevent system faults, take appropriate precautions to avoid PC viruses and similar.



2. Unpacking and installation

2.1 Unpacking and inspection

Check box and contents for damage

When the instrument is received please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty please contact your local distributor. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment

The Callisto™ comes in its own shipping carton, which is specially designed for the Callisto™. Please keep this carton. It will be needed if the instrument has to be returned for service.
If service is required, please contact your local distributor.

Reporting Imperfections

Inspect before connection

Prior to connecting the product it should once more be inspected for damage. All of the cabinet and the accessories should be checked visually for scratches and missing parts.

Report immediately any faults

Any missing part or malfunction should be reported immediately to the supplier of the instrument,along with the invoice, serial number, and a detailed report of the problem. In the back of this manual you will find a "Return Report" where you can describe the problem.

Please use "Return Report"

Please realise that if the service engineer does not know what problem to look for he may not find it, so using the Return Report will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.

Storage

If you need to store the Callisto™ for a period, please ensure it is stored under the conditions specified in the technical specifications:

2.2 Marking

The following marking can be found on the instrument:

	Refer to instruction manual Please refer to warning and pre-cautions
	WEEE 2002/96/EC Please refer to warning and pre-cautions
	Type B applied parts. Patient applied parts that are not conductive and can be immediately released from the patient.
	Year of manufacture.

2.3 Callisto™ - connection panel dictionary



Position:	Symbol:	Function:
1	Insitu L.	Connection of Insitu Headset Left
2	Insitu R.	Connection of Insitu Headset Right
3	TB/Coupler	Socket for talk back microphone or coupler base
4	TF	Socket for talk forward or microphone
5	Monitor	Socket for monitor headset
6	FF	Socket for free field speaker
7	Bone	Socket for bone conductor
8	Left	Socket for left AC headphone/Insert phone
9	Right	Socket for right AC headphone/Insert phone
10	Pat. Resp.	Socket for patient response button
11	USB/PC	Socket for USB cable to PC

2.4 Callisto™ - indicators:

GREEN-Light:	Ready
RED-Light:	Indicates right ear selected in REM and HIT module
BLUE-Light:	Indicates left ear selected in REM and HIT module
PURPLE-Light:	Indicates both ears selected in REM and HIT module
LIGHT BLUE-Light:	Indicates that the Callisto™ is not correctly connected to the Callisto™ Suite

2.5 Software installation

To know before starting the installation.

You must have administrative rights to the computer on which you are installing the Callisto™ Suite.



DO NOT connect the Callisto™ hardware to the computer before the software has been installed!
Please also refer to the section "Warnings and precautions"

What you will need:

1. Callisto™ Suite Installation USB Drive
2. USB Cable
3. Callisto™ Hardware

Supported Noah Office Systems We are compatible with all Noah-integrated office systems which are running on Noah and Noah engine.

To use the software with a database, make sure the database is installed prior to the Callisto™ Suite installation. Follow the manufacturer's installation instructions provided to install the relevant database. Note that if you are using AuditBase you must ensure to launch this office system prior to this installation of the Callisto™ Suite.

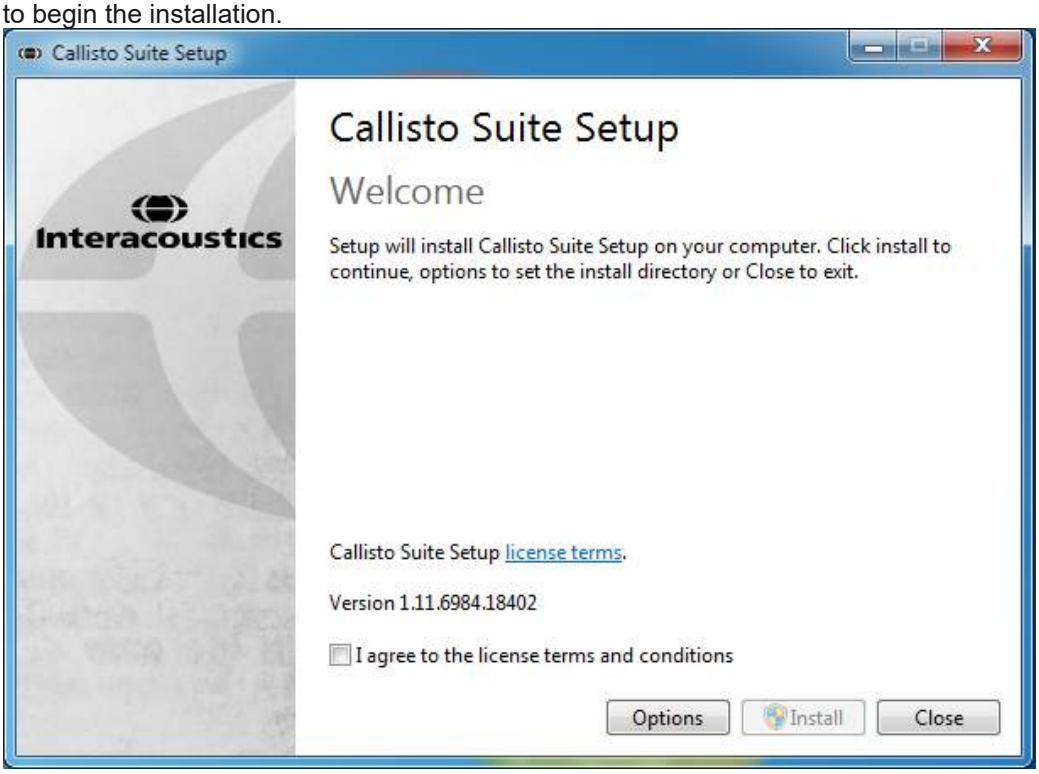
Installation of various Windows® versions

Installation on Windows® 7 (32 and 64 bit), Windows® 8 (32 and 64 bit) and Windows® 10 (32 et 64 bits) systems are supported. Note that with Windows® "N" versions, Media Player needs to be in- stalled manually for the software suite to run

2.5.1 Software installation Windows®7 and Windows®8

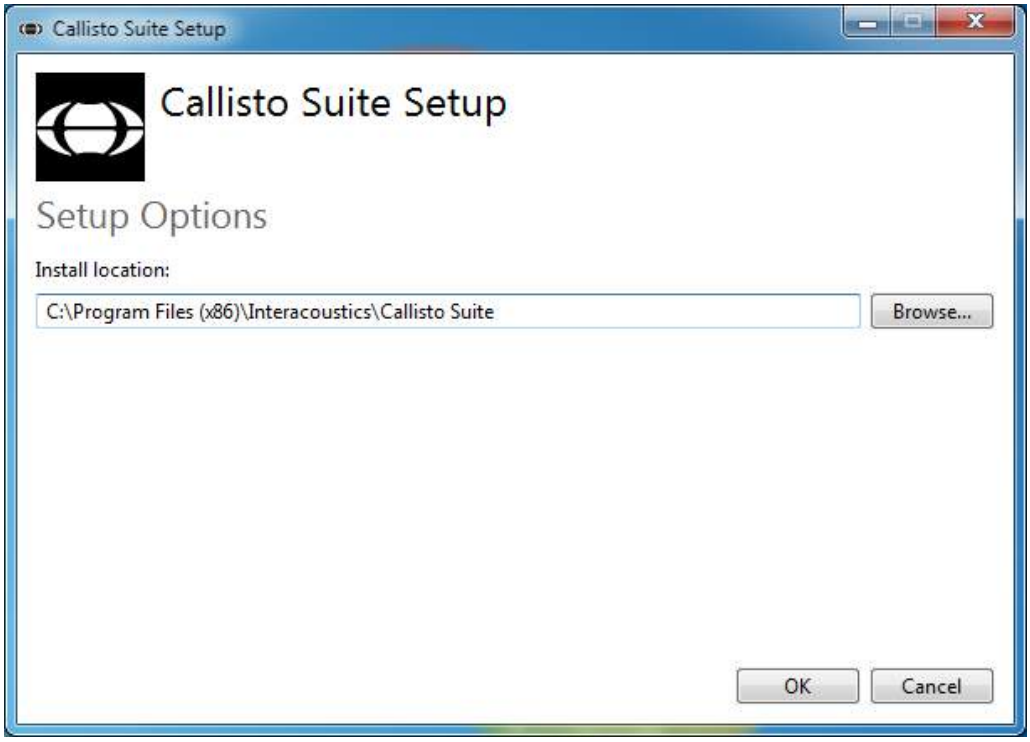
Insert the installation USB drive and follow the steps below to install the Callisto™ Suite software. To find the installation file; click “Start”, then go to “My Computer” and double click the USB drive to view the contents of the installation USB. Double click the “setup.exe” file to initiate the installation.

1. Wait for the dialog shown below to appear, you must accept the license terms and conditions ahead of installing. On checking the box to accept this, the Install button will become available, click “Install” to begin the installation.

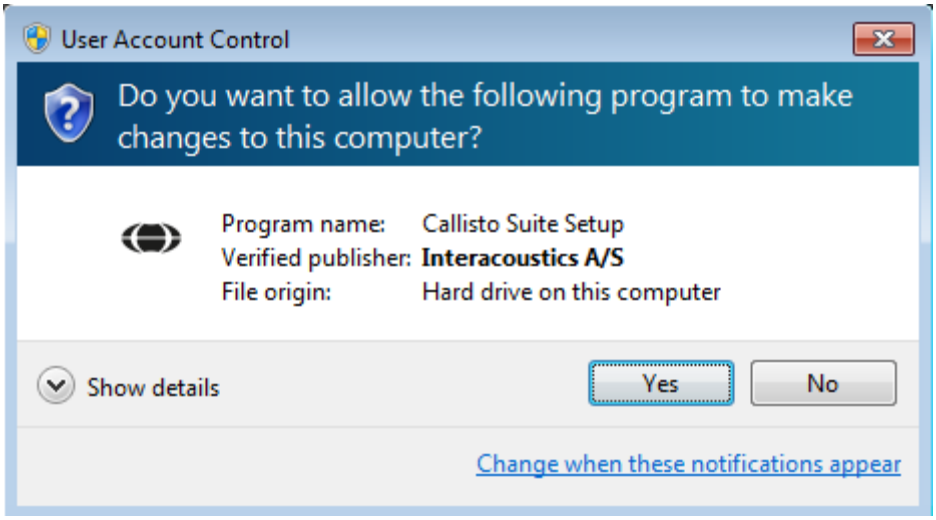




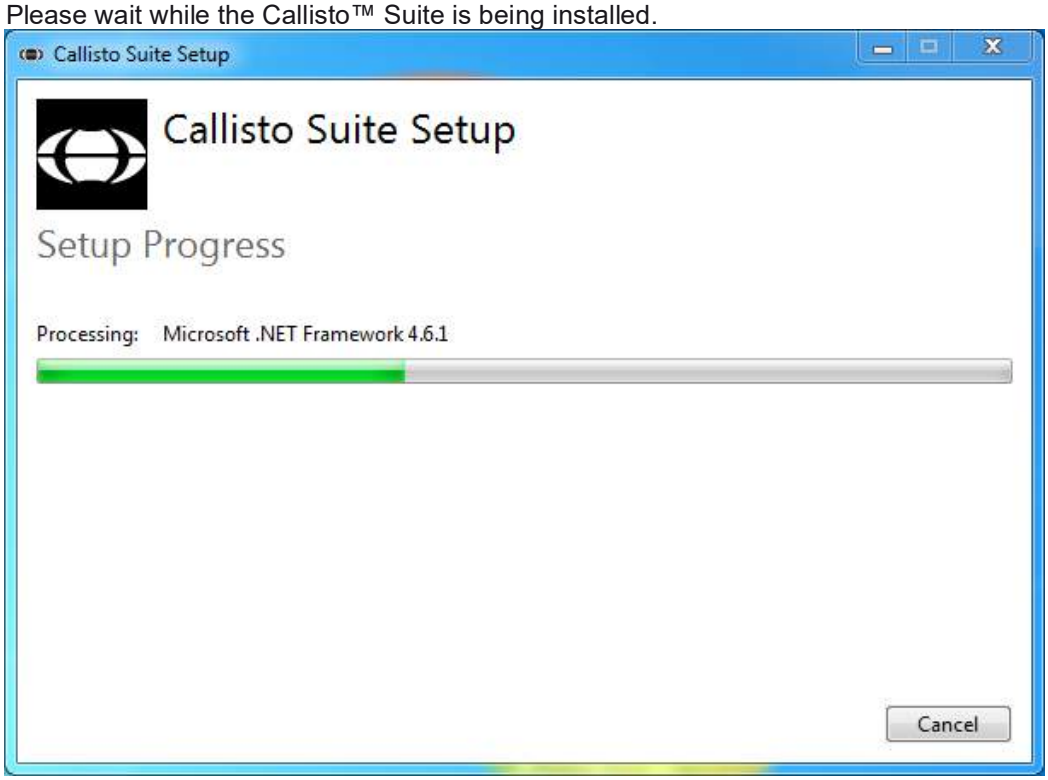
Should you wish to install the software to a different location than the default then please click on ’Options’ ahead of ’Install’



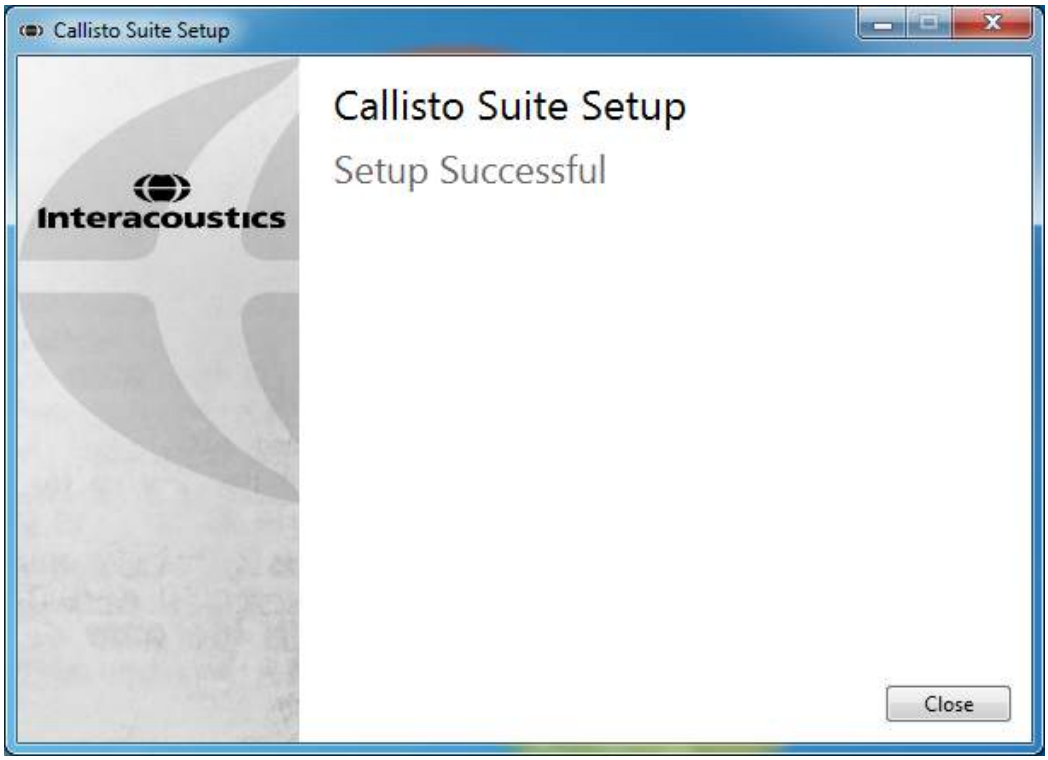
2. Depending on your Windows User Account settings the following dialog may appear. Select “Yes” to continue the installation.



3. Please wait while the Callisto™ Suite is being installed.



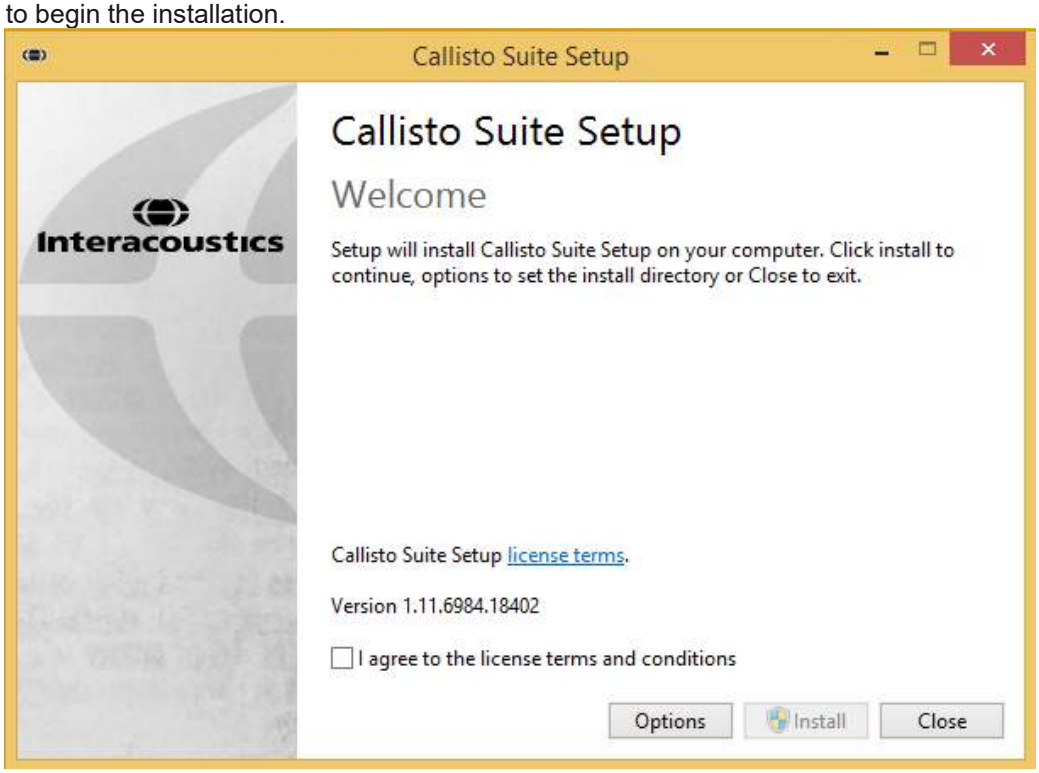
4. When the installation is complete, the dialog box below is shown. Click “Close” to finish the installation. The Callisto™ Suite is now installed.

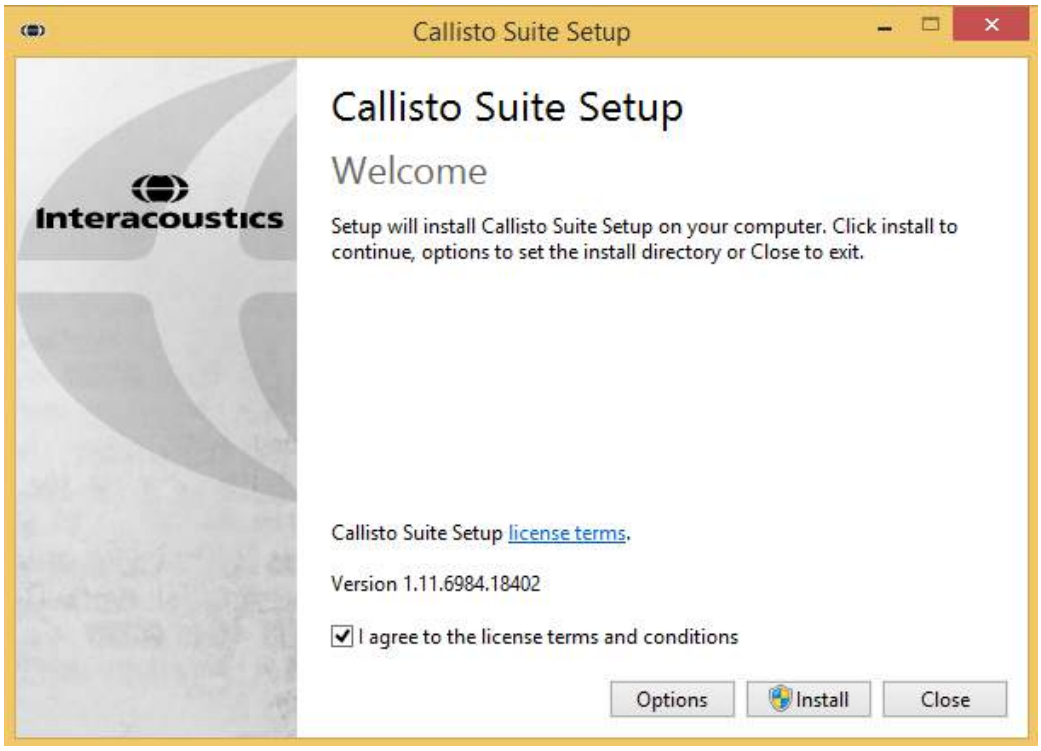


2.5.2 Software installation Windows®8.1

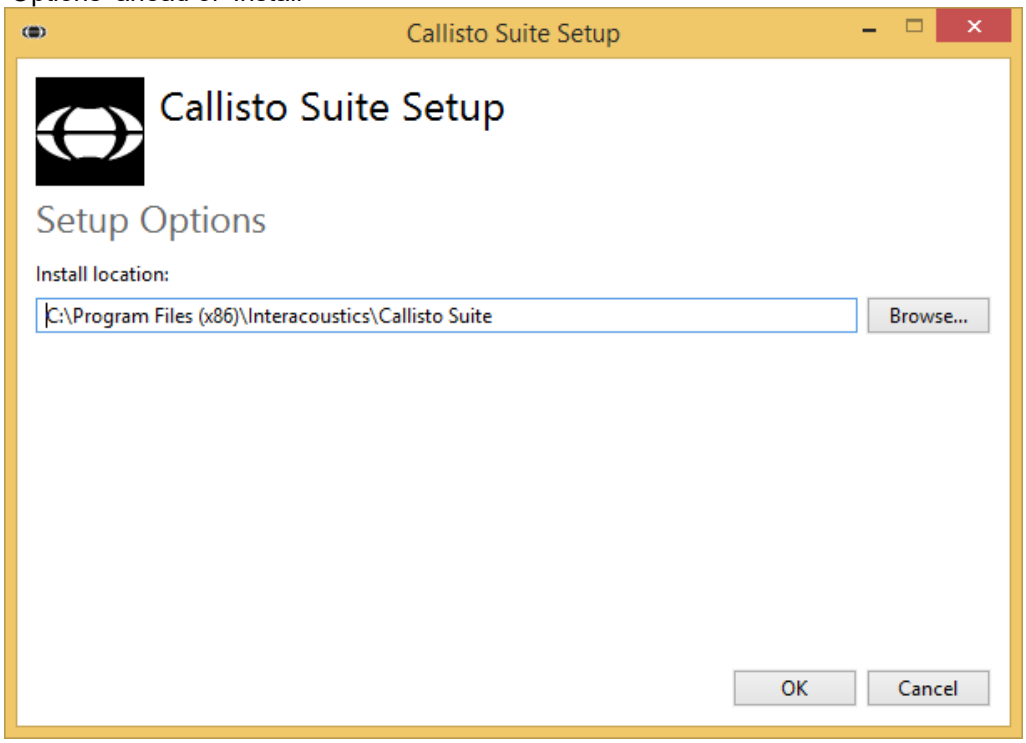
Insert the installation USB drive and follow the steps below to install the Callisto™ Suite software. To find the installation file; click “Start”, then go to “My Computer” and double click the USB drive to view the contents of the installation USB. Double click the “CallistoSuiteSetup.exe” file to initiate the installation.

1. Wait for the dialog shown below to appear, you must accept the license terms and conditions ahead of installing. On checking the box to accept this, the Install button will become available, click “Install” to begin the installation.

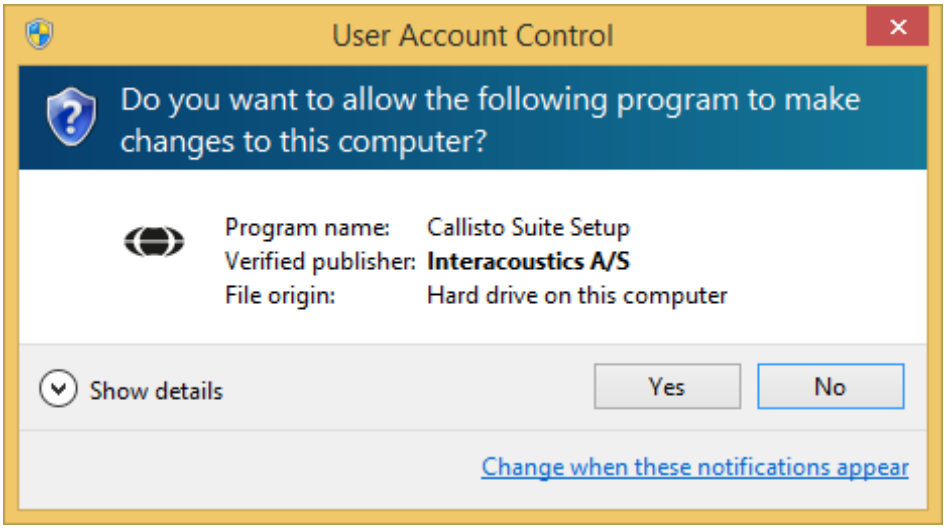




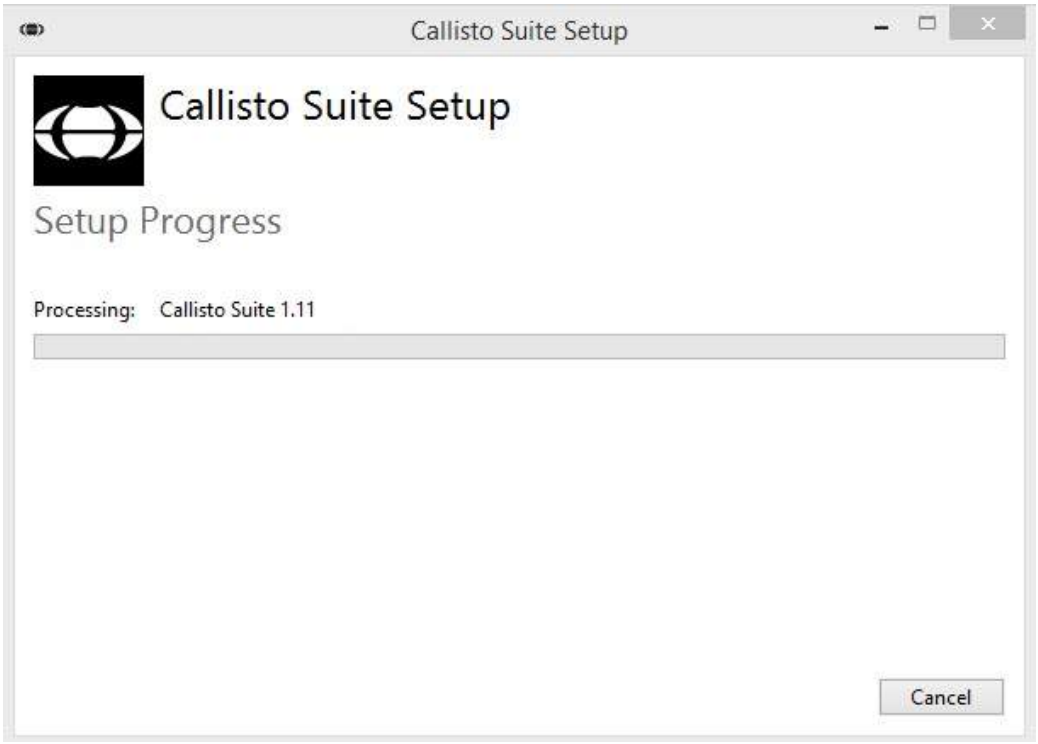
Should you wish to install the software to a different location than the default then please click on 'Options' ahead of 'Install'



2. Depending on your Windows User Account settings the following dialog may appear. Select "Yes" to continue with the installation.



3. Please wait while the Callisto™ Suite is being installed.



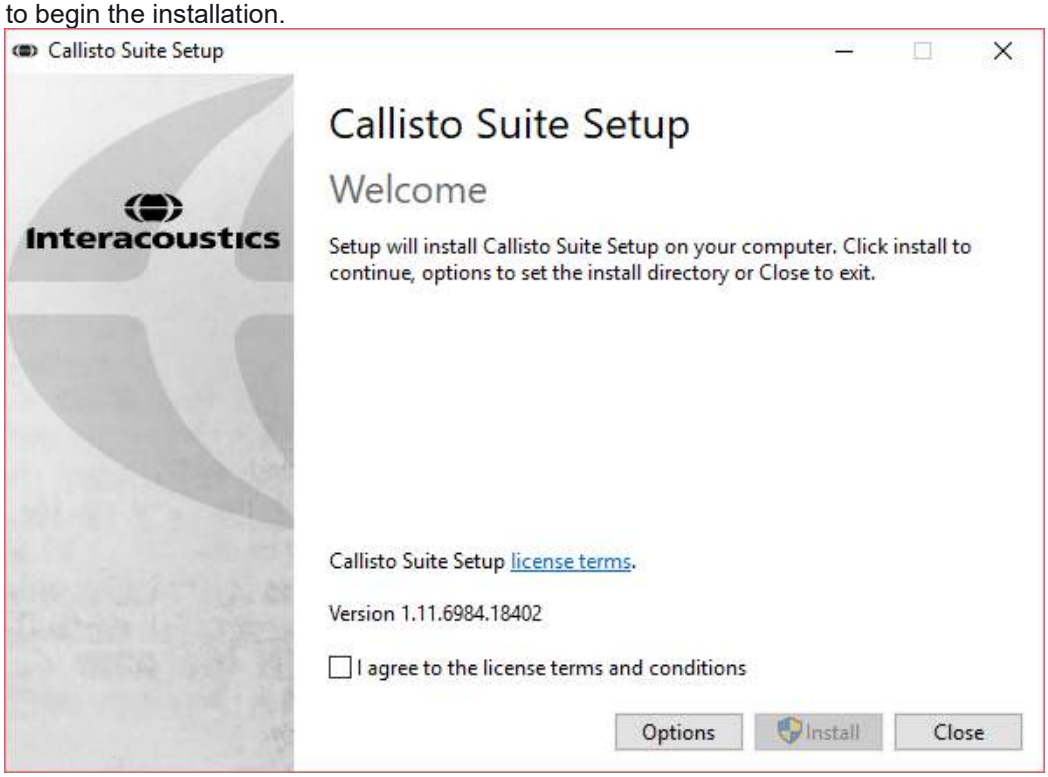
4. When the installation is complete, the dialog box below is shown. Click “Close” to finish the installation. The Callisto™ Suite is now installed.

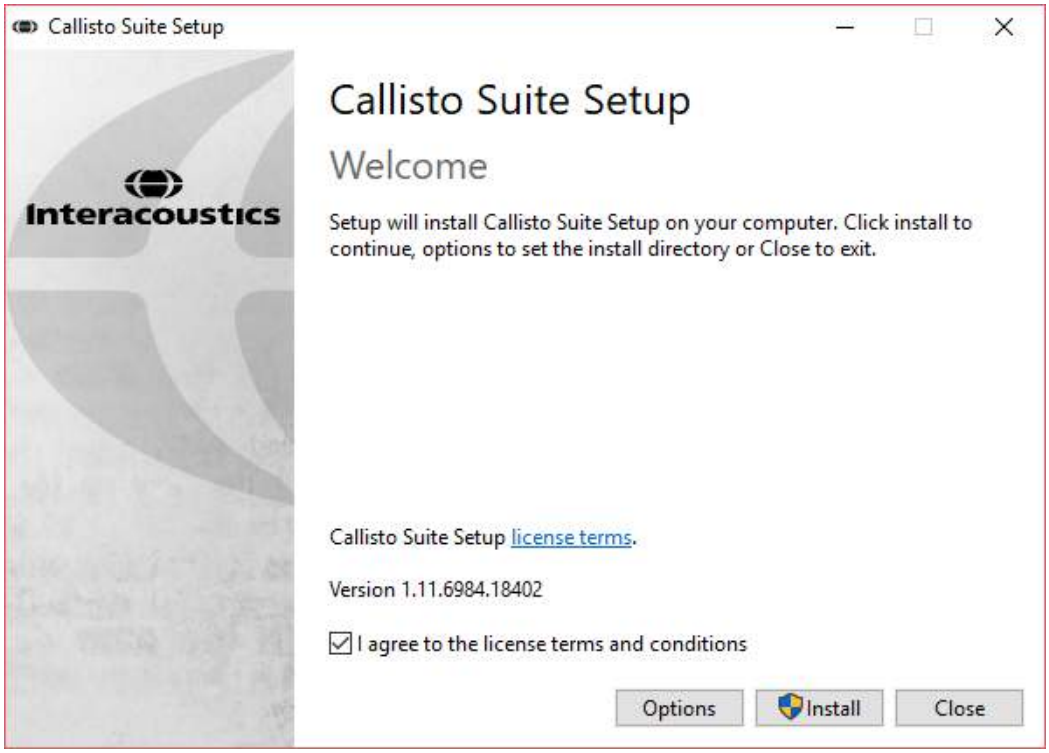


2.5.3 Software installation Windows®10

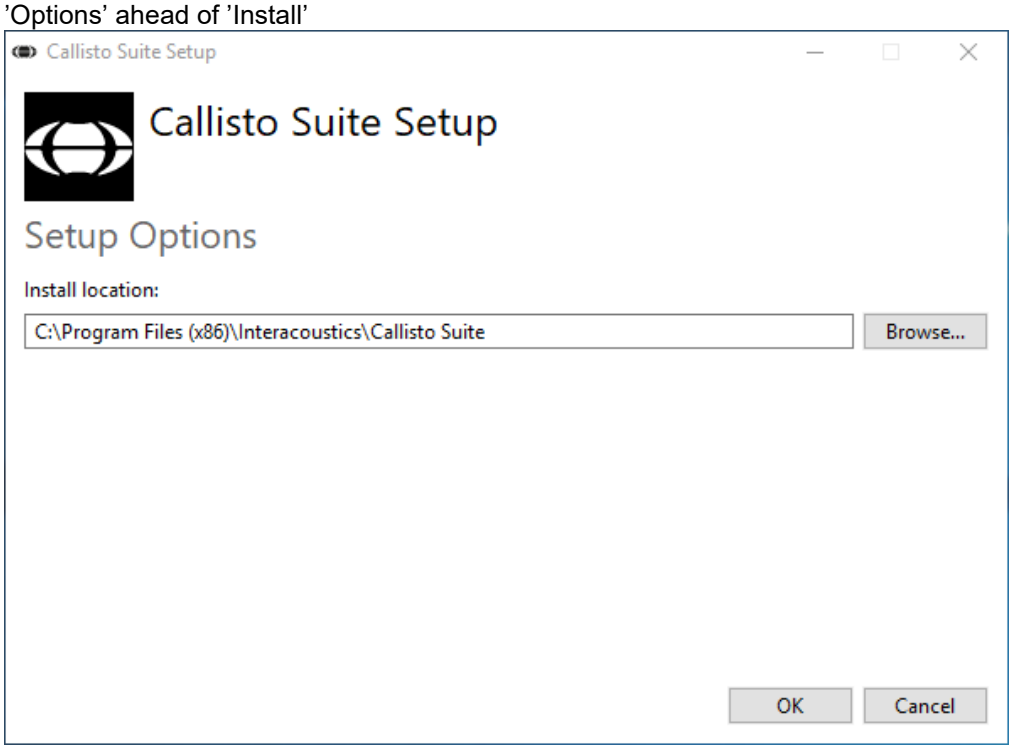
Insert the installation USB drive and follow the steps below to install the Callisto™ Suite software. To find the installation file; click “Start”, then go to “My Computer” and double click the USB drive to view the contents of the installation USB. Double click the “CallistoSuiteSetup.exe” file to initiate the installation.

1. Wait for the dialog shown below to appear, you must accept the license terms and conditions ahead of installing. On checking the box to accept this, the Install button will become available, click “Install” to begin the installation.

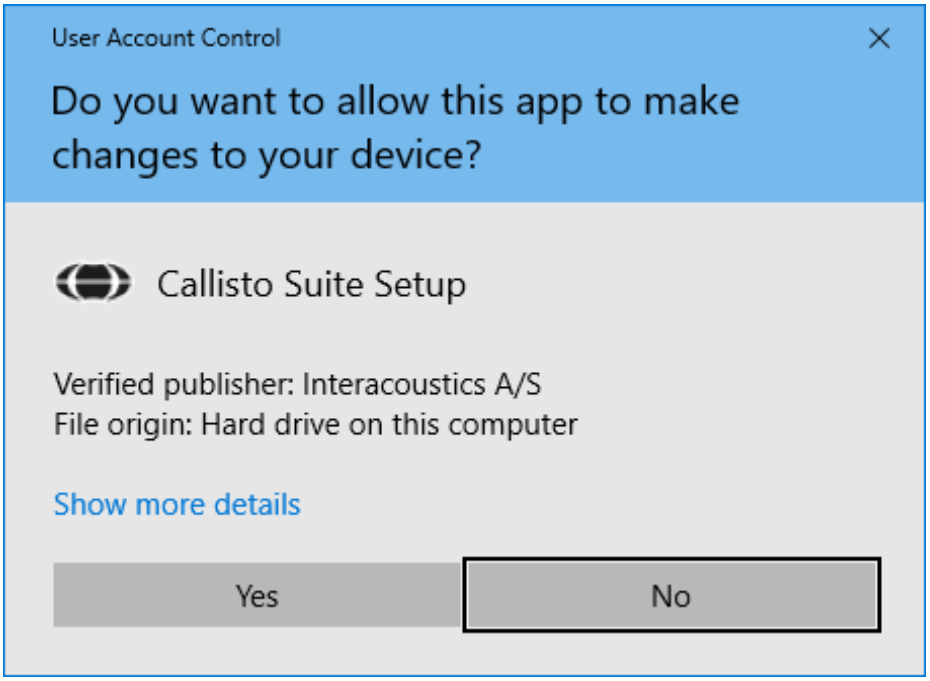




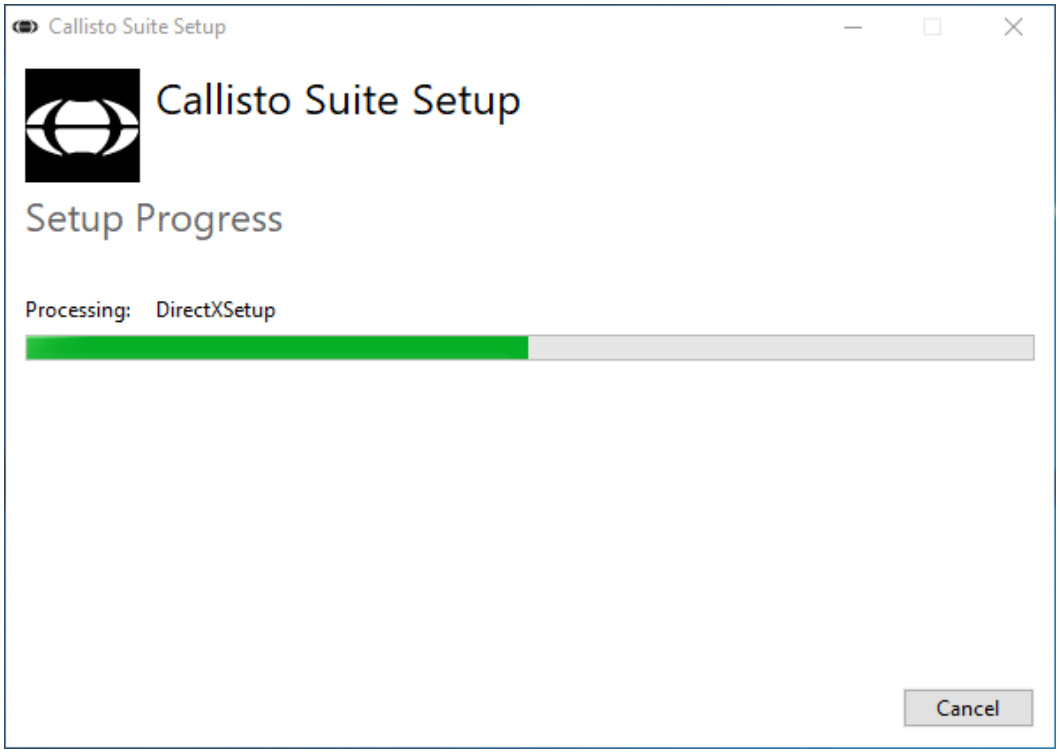
Should you wish to install the software to a different location than the default then please click on 'Options' ahead of 'Install'



2. Depending on your Windows User Account settings the following dialog may appear. Select "Yes" to continue with the installation.



3. Please wait while the Callisto™ Suite is being installed.



4. When the installation is complete, the dialog box below is shown. Click “Close” to finish the installation. The Callisto™ Suite is now installed.



2.6 Driver installation

Now that the Callisto™ Suite software is installed you must install the driver for the Callisto™.

1. Connect the Callisto™ hardware to the PC via the USB connection.
2. The system will now automatically detect the hardware and a pop- up will appear on the task bar near the clock indicating that the driver is installed and the hardware is ready for use.
3. To finalize the installation process, start the Callisto™ Suite. Select the desired Regional settings and Language when the pop-up below appears.



2.6.1 Sound device settings

If the sound card has not been correctly configured during the installation, the dialog below will appear the first time you open the Callisto™ Suite. To automatically setup your sound device select your preferred device from the list of click “Set as default sound device”. After automatically setting the default sound device you must restart the suite in order for the changes to take effect.

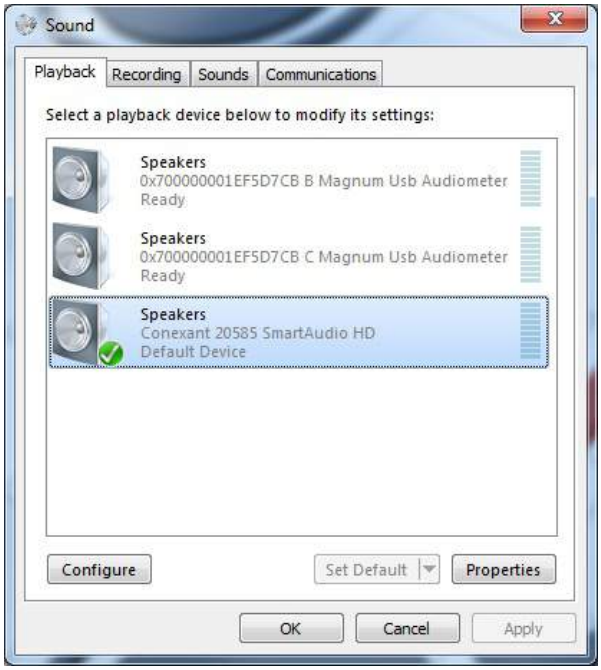


For manual setup click “Show guide to set the sound device manually”. Now select “Video instructions” or “Written instructions” depending on your preference and follow the instructions to change the sound card settings.

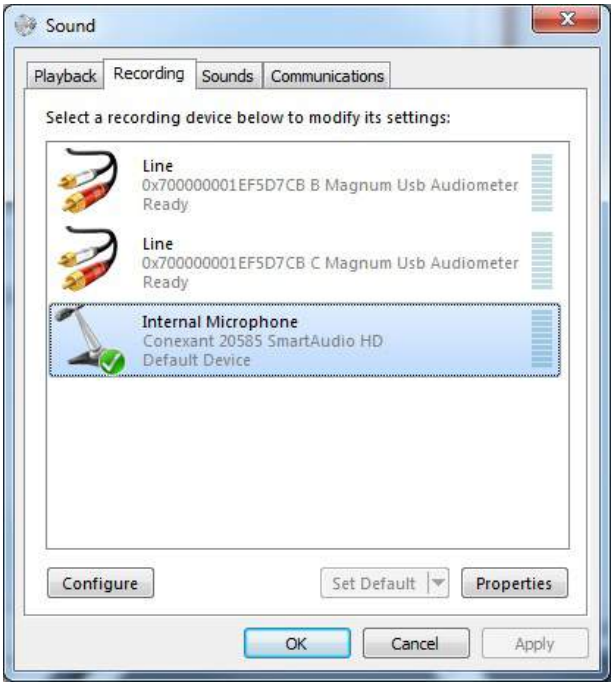
2.6.2 Sound device settings for Windows®7/ Windows®8/Windows®10

In the “Start” menu find the “Control Panel” and select “Sound”.

1. In the “Playback” tab make sure to set the default playback device to the original default device. In this case “SoundMAX Integrated Digital HD Audio Default Device.



2. In the “Recording” tab make sure to set the default recording device to your original device. In this case “Microphone USB Audio Device”.



2.7 Using with databases

2.7.1 Noah 4

If you are using HIMSA's Noah4 Office System, the Callisto™ software will install itself automatically in the menu bar on the Noah4 start page, along with all the other software modules.

2.7.2 Working with OtoAccess®

For further instructions about working with OtoAccess®, please see the OtoAccess® operation manual

2.8 Standalone version

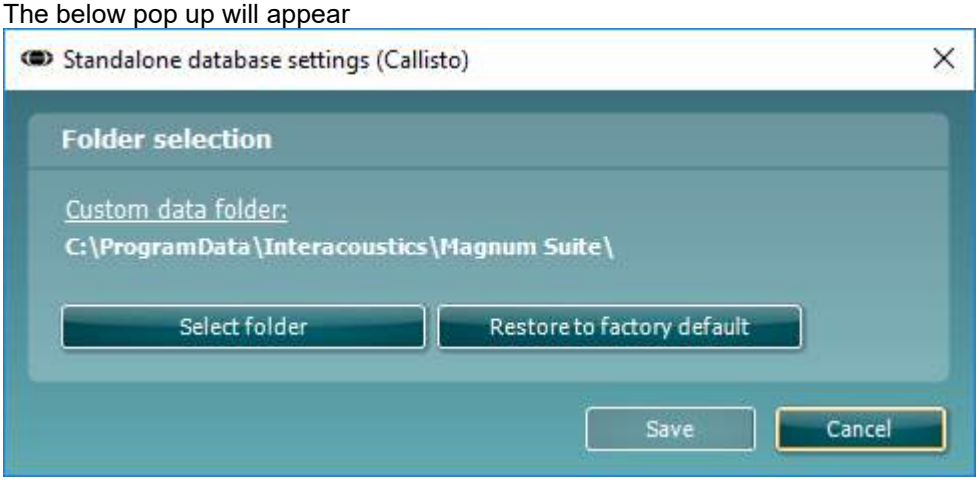
If you do not have Noah on your computer you can directly launch the software suite as a stand-alone module. However, you will not be able to save your recordings when using this way of working.

2.9 How to configure an alternative data recovery location

The Callisto™ Suite has a backup location for data to be written in the case that the software is accidentally terminated or the system crashes. The following location is the default storage folder C:\ProgramData\Interacoustics\Callisto Suite\, however this can be changed by following the below instructions.

NOTE: This feature can be used to change the recovery location when you are working through a database as well as the standalone save location.

1. Go to C:\Program Files (x86)\Interacoustics\Callisto Suite
2. In this folder find and launch the executable program titled FolderSetupCallisto.exe
3. The below pop up will appear



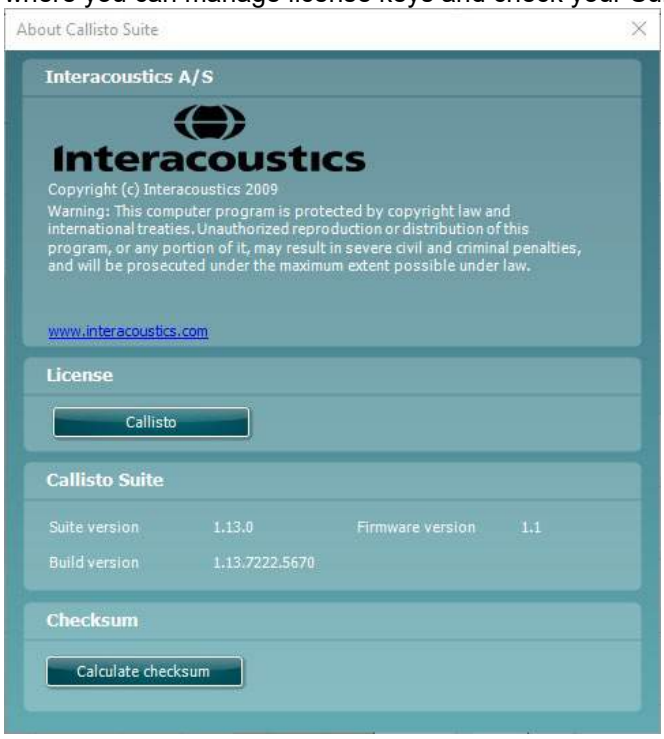
4. Using this tool you can specify the location you wish to store the standalone database or the recovery data by clicking on the 'Select Folder' button and specifying the desired location.
5. Should you wish to revert the data location to the default then simply click on the 'Restore factory default' button.

2.10 License

When you receive the product it already contains the licenses to access the ordered software modules. If you would like to add additional modules, please contact your dealer.

2.11 About Callisto™ Suite

Should you go to **Menu > Help > About** then you will see the below window. This is the area of the software where you can manage license keys and check your Suite, Firmware and Build Versions.



Also in this window you will find the Checksum section which is a feature designed to help you identify the integrity of the software. It works by checking the file and folder content of your software version. This is using an SHA-256 algorithm.

On opening the checksum you will see a string of characters and numbers, you can copy this by double clicking on it.

3. Operating instructions

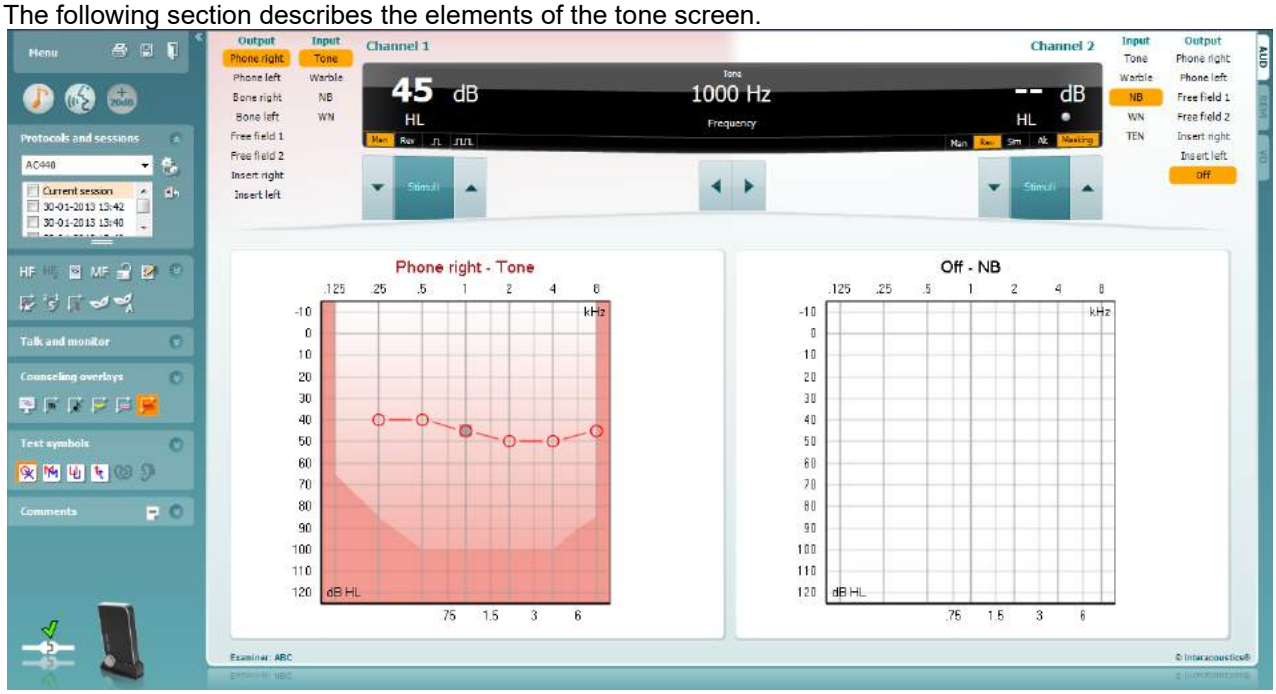
The instrument is switched on automatically when the USB cable is connected to both the Callisto™ and the PC. A green indication light on the Callisto™ will indicate that it is “ON”. When operating the instrument, please observe the following general precautions:



1. The intended operators of the instrument are ENT doctors, Audiologists and other professionals with similar knowledge. Using the instrument without adequate knowledge may lead to erroneous results and may endanger the patients’ hearing.
2. Only recorded speech material with a stated relationship with the calibration signal should be used. In the calibration of the instrument it is assumed that the calibration signal level is equal to the average level for the speech material. If this is not the case, the calibration of the sound pressure levels will be invalid and the instrument needs recalibration.
3. It is recommended that the disposable foam eartips supplied with the optional IP30, E·A·R Tone 3A or E·A·R Tone 5A insert transducers are replaced after each client tested. Disposable foam eartips also ensure that sanitary conditions exist for each of your clients, and that periodic cleaning of a headband or cushion is no longer required.
4. The instrument must warm up for at least 3 minutes in room temperature before use.
5. Be sure to use intensity levels of the presentation signal which will be acceptable for the patient.
6. The transducers (headphones, bone conductor, etc.) supplied with the instrument are calibrated to this instrument. Exchange of transducers requires a new calibration.
7. It is advised that you apply masking when performing Bone Conduction Audiometry to ensure that correct results are obtained.
8. It is recommended that parts which are in direct contact with the patient (e.g. earphone cushions) are subjected to standard disinfecting procedure between patients. This includes physically cleaning and use of a recognized disinfectant. Individual manufacturer's instruction should be followed for use of this disinfecting agent to provide an appropriated level of cleanliness.
9. To establish conformity with the IEC 60645-2 standard, it is important that the speech input level is adjusted to 0VU. It is equally important that any free field installation is calibrated at the site where it is used and under the conditions that exists during normal operation.
10. For maximum electrical safety, remove the USB cable when it is left unused.

3.1 AC440 using the tone screen elements

The following section describes the elements of the tone screen.





Menu provides access to Print, Edit, View, Tests Setup, and Help.



Print allows for printing the data acquired during the session



Save & New Session saves the current session in Noah or OtoAccess® and opens a new one.



Save & Exit saves the current session in Noah or OtoAccess® and exits the Suite.



Collapse the left side panel.



Go to Tone Audiometry activates the tone screen when in another test.



Go to Speech Audiometry activates the speech screen when in another test.



Extended Range +20 dB extends the testing range and can be activated when the testing threshold reaches 50 dB below the maximum level of the headset. The shaded area in the graph illustrates the maximum intensity the system will allow. This is a reflection of the transducer calibration.

Note that the extended range button will flash when it needs activation for reaching higher intensities.

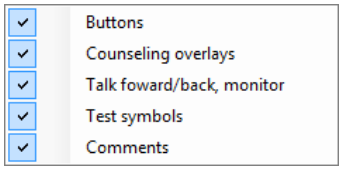
To switch on the extended range automatically, select the **Switch extended range on automatically** by going to the setup menu.



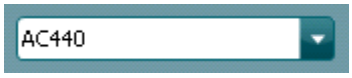
Fold an area so that it only shows the label or the buttons of that area.



Unfold an area so that all buttons and labels are visible.



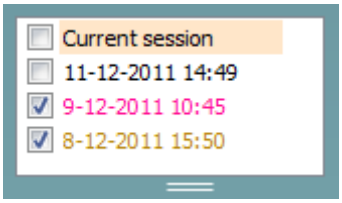
Show/hide areas can be found by right mouse clicking on one of the areas. The visibility of the different areas as well as the space that they take on the screen is locally saved to the examiner.



List of Defined Protocols allows for selecting a test protocol for the current test session. Right mouse click on a protocol allows the current examiner to set or deselect a default startup protocol. Please refer to the "Additional Information" document for more information about protocols and protocol setup.



Temporary Setup allows for making temporary changes to the selected protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the protocol will be followed by an asterisk (*).



List of historical sessions accesses historical sessions for comparison purposes. The audiogram of the selected session, indicated by the orange background, is shown in colours as defined by the used symbol set. All other audiograms that are selected by check marks show on screen in the colours as indicated by the text colour of the date and time stamp. Note that this listing can be resized by dragging the double lines up or down.



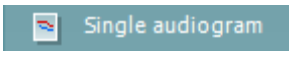
Go to Current Session brings you back to the current session.



High Frequencies[1] show frequencies on the audiogram (up to 16 kHz for the Callisto™). However, you will only be able to test in the frequency range the high frequency headset is calibrated for.



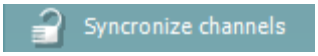
High Frequency Zoom activates high frequency testing and zooms in on the high frequency range. Please refer to the Callisto™ "Additional Information" document for more information on HF Audiometry



Toggle between Single and Dual Audiogram button toggles between viewing the audiogram as one combined graph or two separate graphs.

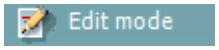


Multi Frequency[2] activates Multi Frequency testing. The frequency steps can be adjusted in the AC440 setup.

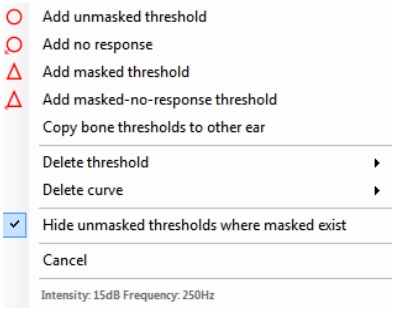


Synchronize channels locks the two channels together. This function may be used to perform synchronous masking.

[1] HF requires an additional feature for the AC440. If not purchased, the button is greyed out.
[2] MF requires additional feature for the AC440. If not purchased, the button is greyed out.



Edit Mode button activates the editing function. Left clicking on the graph will add/move a point to the position of the cursor. If right clicking on a specific stored point a context menu appears offering you the following options:





Mouse controlled audiometry enables you to do the audiometry using the mouse only. Left click on the mouse to present the stimulus. Right click on the mouse to store the result.



The **dB step size** button indicates to which dB step size the system is currently is set. It rotates between 1 dB, 2 dB and 5 dB step sizes.

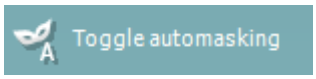


The **hide unmasked threshold** will hide those unmasked thresholds where masked thresholds exist.



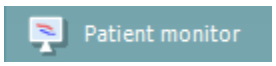
Toggle Masking Help will activate or deactivate the Masking Help feature.

For more information on Masking Help, please refer to the Callisto™ “Additional Information” or the “Masking Help Quick Guide” documents.



Toggle Automasking will activate or deactivate the Automasking feature.

For more information on Automasking, please refer to the Callisto™ “Additional Information” or the “Masking Help Quick Guide” documents.



The **Patient monitor** opens an always-on-top window with the tone audiograms and all its counselling overlays shown. The size and position of the patient monitor gets saved for each examiner individually.



Talk Forward activates the Talk Forward microphone. The arrow keys can be used to set the talk forward level through the currently selected transducers. The level will be accurate when VU meter indicates to be at zero dB.



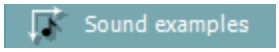
Selecting the **Monitor Ch1** and/or **Ch2** check boxes allow you to monitor one or both channels through an external loudspeaker/headset connected to the monitor input. The monitor intensity is adjusted using the arrow keys.



The **Talk back** check box enables you to listen to the patient. Note that you need to be equipped with a microphone connected to the talk back input and an external loudspeaker/headset connected to the monitor input.



The **Phonemes** counselling overlay shows phonemes as it is set up in the protocol that is currently in use.



The **Sound examples** counselling overlay shows pictures (png-files) as they are set up in the protocol that is currently in use.



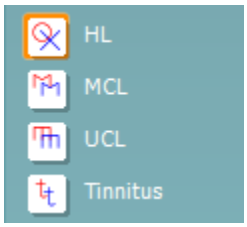
The **Speech banana** counselling overlay shows the speech area as it is set up in the protocol that is currently in use.



The **Severity** counselling overlay shows the degrees of hearing loss as it is set up in the protocol that is currently in use.



The **Max. testable values** shows the area beyond the maximum intensity the system allows. This is a reflection of the transducer calibration and depends on the extended range being activated.



Selecting **HL**, **MCL**, **UCL** or **Tinnitus** sets the symbol types that are currently in use by the audiogram. HL stands for hearing level, MCL stands for most comfortable level and UCL stands for uncomfortable level. Note that these buttons show the unmasked right and left symbols of the currently selected symbol set.

Each type of measurement is saved as a separate curve.



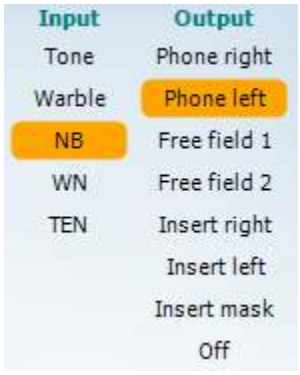
In the **Comments** section you can type comments related to any audiometric test. The used space by the comments area can be set by dragging the double line with your mouse. Pressing the **Report editor** (1) button opens a separate window for adding notes to the current session. The report editor and comment box contain the same text. In case the formatting of the text is important, this can only be set within the report editor.

After saving the session, changes can only be made within the same day until the date changes (at midnight). **Note:** these timeframes are limited by HIMSA and the Noah software, and not by Interacoustics.



The **Output** list for channel 1 provides the option to test through head phones, bone conductor, free field speakers or insert phones. Note that the system only shows the calibrated transducers.
The **Input** list for channel 1 provides the option to select pure tone, warble tone, narrow band noise (NB) and white noise (WN).

Note that the background shading is according to the side that is selected, red for right and blue for left.



The **Output** list for channel 2 provides the option to test through head phones, free field speakers, insert phones or insert masking phone. Note that the system only shows the calibrated transducers.
The **Input** list for channel 2 provides the option to select pure tone, warble tone, narrow band noise (NB), white noise (WN) and TEN noise[3].

Note that the background shading is according to the side that is selected, red for right, blue for left, and white when off.



Pulsation allows for single and continuous pulsating presentation. The duration of the stimulus can be adjusted in the AC440 setup.

[3] TENs test requires an additional license for the AC440. If not purchased, the stimulus is grayed out.



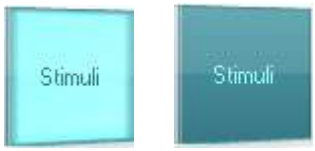
Sim/Alt allows toggling between **Simultaneous** and **Alternate** presentation. Ch1 and Ch2 will present the stimulus simultaneously when Sim is selected. When Alt is selected, the stimulus will alternate between Ch1 and Ch2.



Masking indicates if channel 2 is currently in use as a masking channel and in that way makes sure masking symbols are used in the audiogram. For example in paediatric testing through free field speakers, channel 2 can be set as a second testing channel. Note that a separate store function for channel 2 is available when channel 2 is not used for masking.



dB HL Increase and **Decrease** buttons allows for increasing and decreasing the intensities of channel 1 and 2.
The arrow keys on the PC keyboard can be used for adjusting channel 1 intensities.
PgUp and PgDn on the PC keyboard can be used for adjusting channel 2 intensities.



Stimuli or **attenuator** buttons will light up when the mouse goes over and indicates the active presentation of a stimulus.
A right mouse click in the Stimuli area will store a no response threshold. A left mouse click in the Stimuli area will store the threshold at the current position.
Channel 1 stimulation can also be obtained by pressing the space bar or left Ctrl key on the PC keyboard.
Channel 2 stimulation can also be obtained by pressing the right Ctrl key on the PC keyboard.
Mouse movements in the Stimuli area for both channel 1 and channel 2 can ignored depending on the setup.



Frequency and Intensity display area shows what is currently presented. To the left the dB HL value for channel 1 is shown and to the right for channel 2 In the centre the frequency is displayed.

Notice that the dB dial setting will flash when trying to go louder than the maximum available intensity.



Frequency increase/decrease increases and decreases the frequency respectively. This can also be obtained using the left and right arrow keys on the PC keyboard.

Storing thresholds for channel 1 is done by pressing **S** or by a left mouse click in the Stimuli button of channel 1. Storing a no response threshold can be done by pressing **N** or by a right mouse click on the Stimuli button of channel 1.

Storing thresholds for channel 2 is available when channel 2 is not the masking channel. It is done by pressing **<Shift> S** or by a left mouse click on the Stimuli button of channel 2. Storing a no response threshold can be done by pressing **<Shift> N** or by a right mouse click in the attenuator of channel 2.



The hardware indication picture indicates whether the hardware is connected. **Simulation mode** is indicated when operating the software without hardware.



When opening the Suite the system will search for the hardware. If it does not detect the hardware then the system will automatically continue in simulation mode and the Simulation icon (left) will show in place of the connected hardware indication picture.
The **Examiner** indicates the current clinician who is testing the patient. The examiner is saved with a session and can be printed with the results.

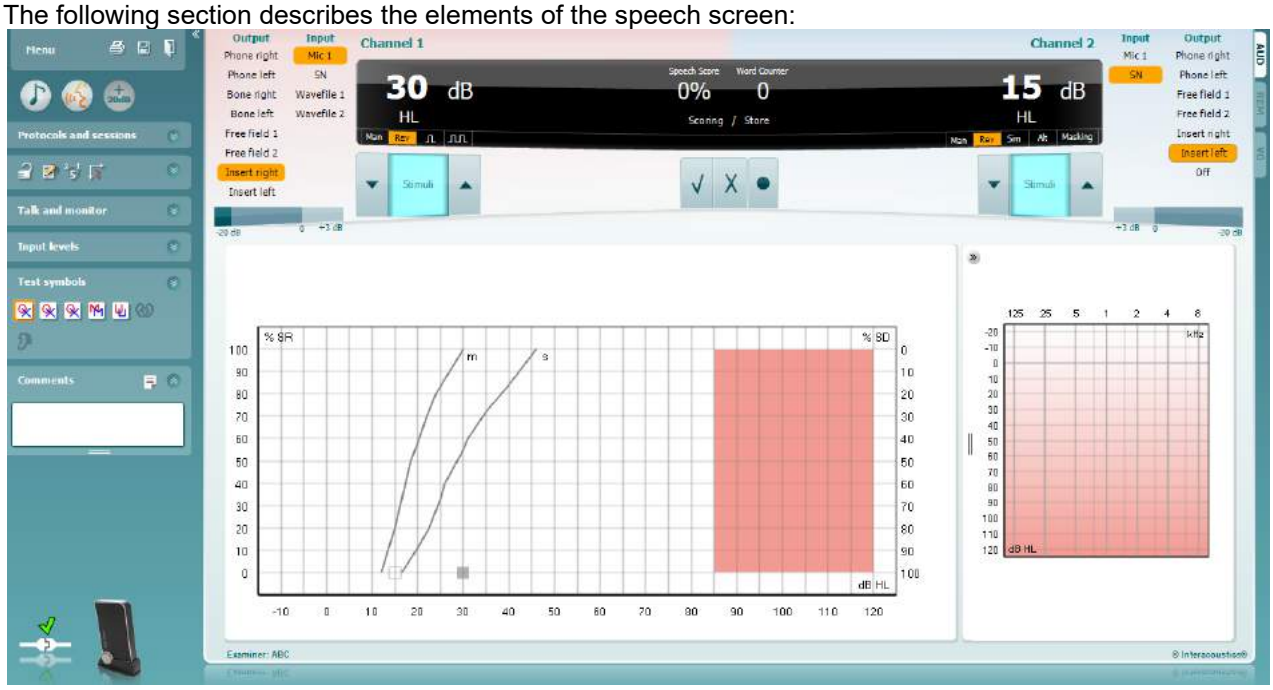




For each examiner is logged how the suite is set up with regards to the use of space in the screen. The examiner will find that the suite starts up looking the same as the last time they used the software. An examiner can also select which protocol must be selected at start up (by right mouse click on the protocol selection list).

3.2 Using the speech screen

The following section describes the elements of the speech screen:

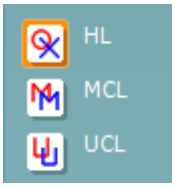




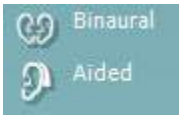
Input Level allow for adjusting the input level to 0 VU for the selected input. This ensures that correct calibration is obtained for the microphone.



WR1, WR2, WR3 (Word Recognition) toggles between different speech lists if selected in the AC440 setup.



MCL & UCL selection allow for toggling between MCL (Most Comfortable Levels) symbols and UCL (Uncomfortable Levels) symbols. The measurements will be saved as separate curves.



Binaural and **Aided** function allows for indicating if the test is performed binaurally or while the patient is wearing hearing aids. This feature is only active in the Speech Audiometry screen.



The **Output** list for channel 1 provides the option to test through the desired transducers. Note that the system only shows the calibrated transducers.

The **Input** list for channel 1 provides the option to select white noise (WN), speech noise (SN), microphone (Mic 1) and wavefile.

Note that the background shading is according to the side that is selected, red for right and blue for left.



Man/Rev Ch1 allows for toggling between Manual and Reverse test modes. In manual mode, the stimulus is presented only when manually activated. In reverse mode, the signal is presented continuously.



The **Output** list for channel 2 provides the option to test through the desired transducers. Note that the system only shows the calibrated transducers.

The **Input** list for channel 2 provides the option to select white noise (WN), speech noise (SN), microphone (Mic 1) and wavefile.

Note that the background shading is according to the side that is selected, red for right, blue for left, and white when off.



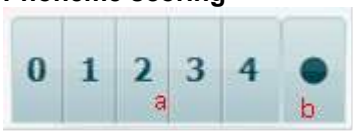
Man/Rev Ch2 allows for toggling between Manual and Reverse test modes. In manual mode, the stimulus is presented only when manually activated. In reverse mode, the signal is presented continuously.

Speech Scoring:



a) **Correct:** A mouse click on this button will store the word as correctly repeated. You can also click on the **Left** arrow key to store as correct.
b) **Incorrect:** A mouse click on this button will store the word as incorrectly repeated. You can also click on the **Right** arrow key to store as incorrect
c) **Store:** A mouse click on this button will store the speech threshold in the speech graph.

Phoneme scoring

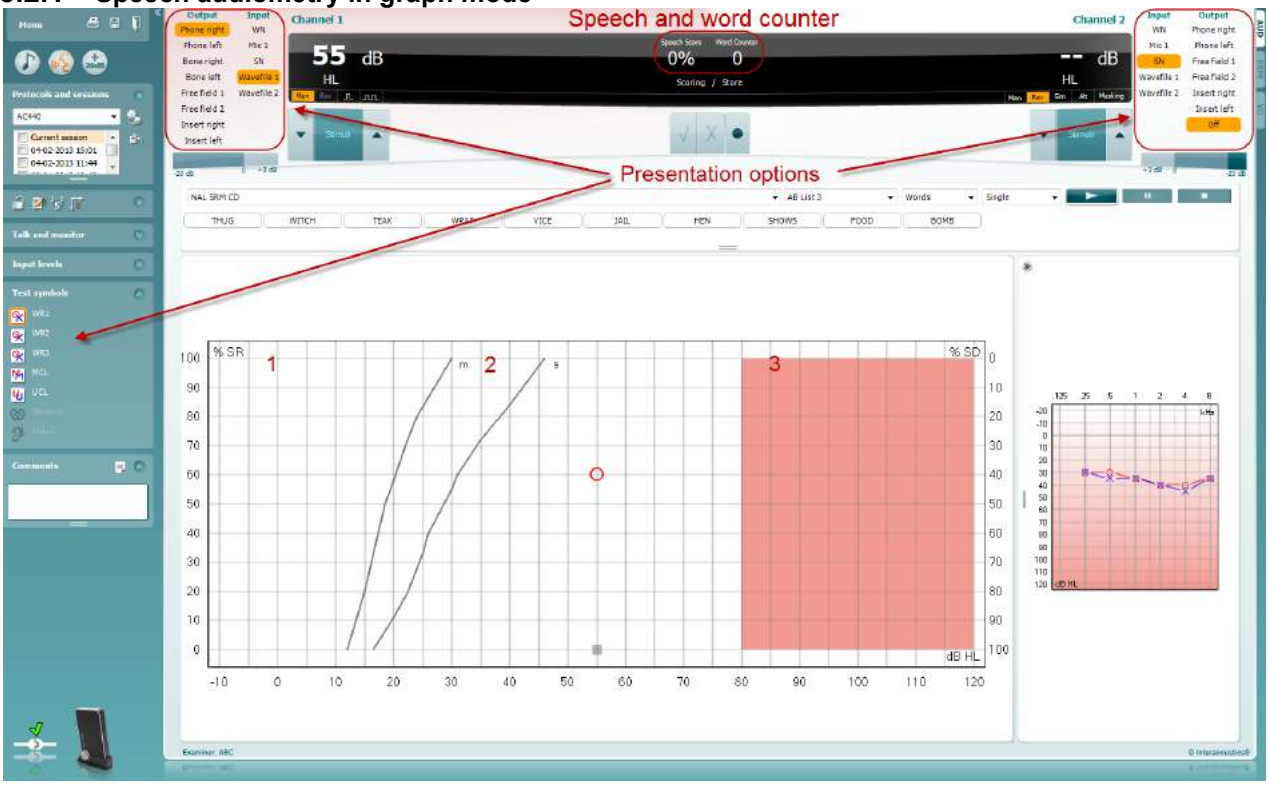


a) **Phoneme scoring:** If phoneme scoring is selected in the AC440 setup, mouse click on the corresponding number to indicate phoneme score. You can also click on the **Up** key to store as correct and **Down** key to store as incorrect.
b) **Store:** A mouse click on this button will store the speech threshold in the speech graph (Press after a full list of words has been presented).



Frequency and Speech Score display shows what is currently presented. On the left the dB value for Ch1 is shown and on the right side for Ch2.
In the centre of the current *Speech Score* in % and the *Word Counter* monitors the number of words presented during the test.

3.2.1 Speech audiometry in graph mode



Graph mode presentation settings under “Test Symbols” in the lower left corner and in the presentation options (Ch1 and Ch2) shows where you can adjust the test parameters during the test.

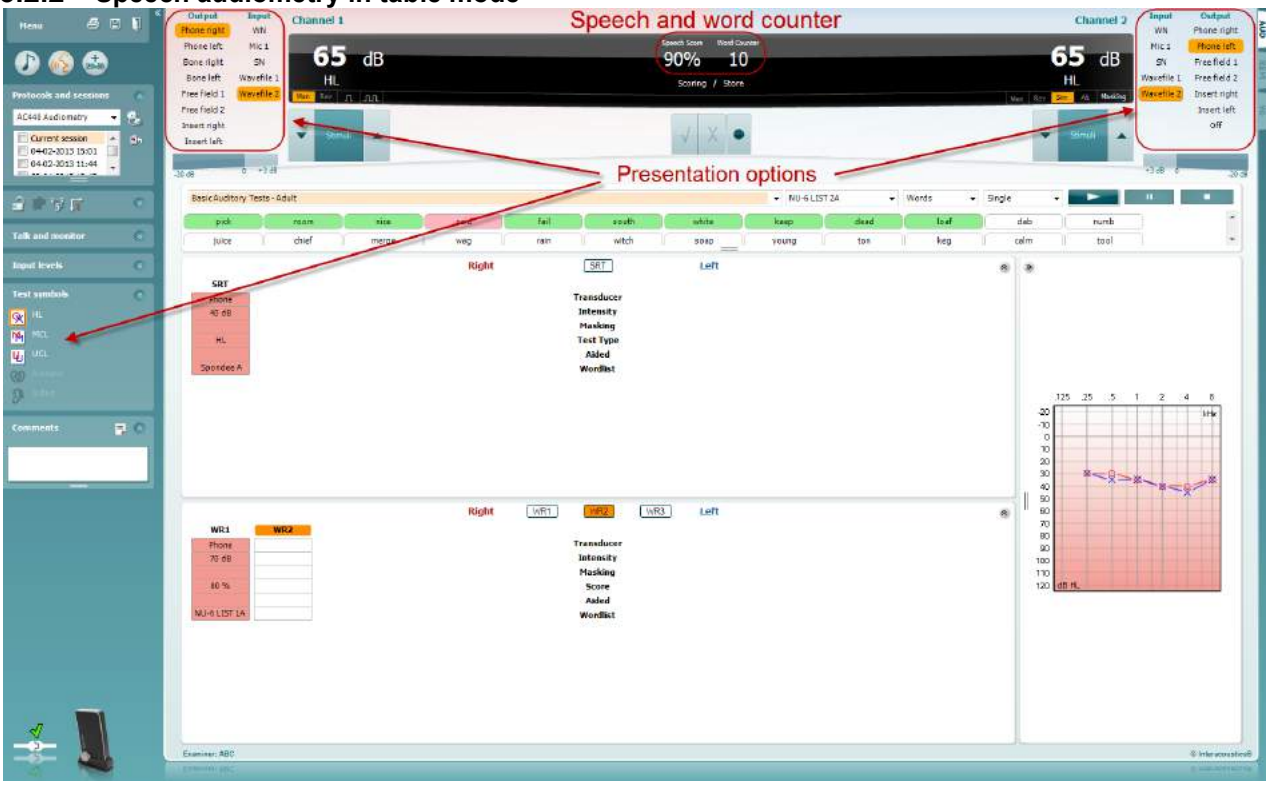
1) **The graph:** The curves of the recorded speech graph will be displayed on your screen.

   The x-axis shows the intensity of the speech signal and the y-axis shows the score in percent. The score is also displayed in the black display in the upper part of the screen, along with a word counter.

2) **The norm curves** illustrate norm values for **S** (Single syllabic) and **M** (Multi syllabic) speech material respectively. The curves can be edited according to individual preferences in the AC440 setup.

3) **The shaded area** illustrates how high in intensity the system will allow. The *Extended Range +20 dB* button can be pressed to go higher. The maximal loudness is determined by the transducer calibration.

3.2.2 Speech audiometry in table mode



The AC440 Table Mode consists of two tables:

1) The **SRT** (Speech Reception Threshold) table. When the SRT test is active, it is indicated in orange SRT.

2) The **WR** (Word Recognition) table. When WR1, WR2, or WR3 is active the corresponding label will be orange WR1.

The SRT table
The SRT table (Speech Reception Threshold table) allows for measuring multiple SRTs using different test parameters, e.g. *Transducer, Test Type, Intensity, Masking,* and *Aided*.
Upon changing *Transducer, Masking*, and/or *Aided* and re-testing, an additional SRT entry will appear in the SRT table. This allows for multiple SRT measurements to be shown in the SRT table.

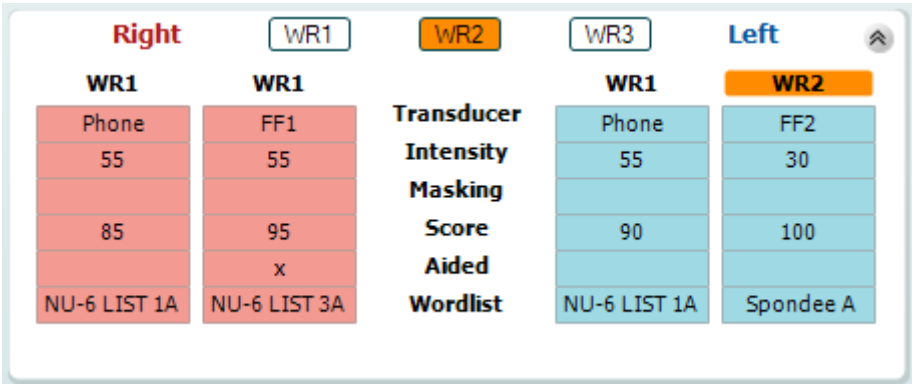
Please refer to the Callisto™ Additional Information document for more information about SRT testing.

Right		SRT	Left	
SRT	SRT		SRT	SRT
Phone	Phone	Transducer	Phone	Phone
30	10	Intensity	10	30
15	15	Masking	15	15
HL	HL	Test Type	HL	HL
	x	Aided	x	
Spondee A	Spondee B	Wordlist	Spondee A	Spondee B

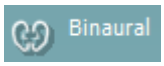
The WR table
The word recognition (WR) table allows for measuring multiple WR scores using different parameters (e.g. *Transducer, Test Type, Intensity, Masking,* and *Aided*).

Upon changing Transducer, Masking, and/or Aided re-testing an additional WR entry will appear in the WR table. This allows for multiple WR measurements to be shown in the WR table.

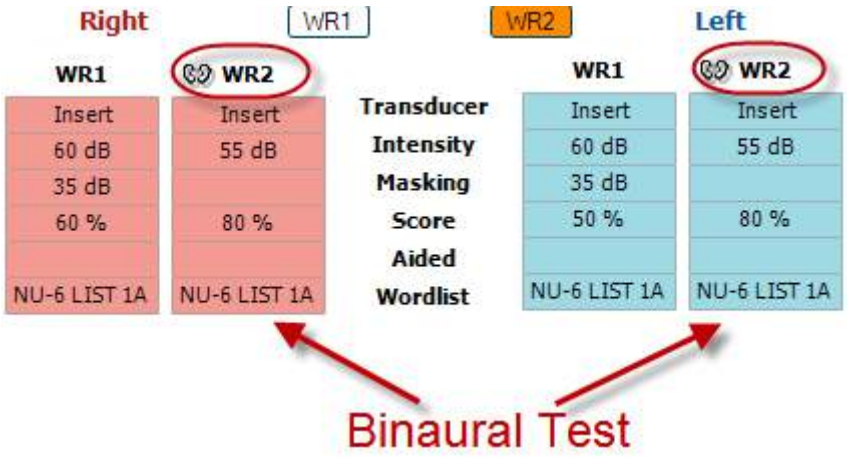
Please refer to the Callisto™ Additional Information document for more information about Word Recognition testing.



Binaural and aided options
To perform binaural speech tests:

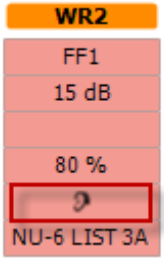
1. Click on either SRT or WR, to choose the test to be conducted binaurally.
2. Ensure that the transducers are set up for binaural testing. For example, insert Right in channel 1 and insert Left in channel 2.
3. Click on 

.
4. Proceed with the test; when stored, results will be stored as binaural results.



To perform an aided test:

1. Select the desired transducer. Typically, aided testing is done in the Free Field. However, in certain conditions, it could be possible to test deeply inserted CIC hearing instruments under headphones, which would show ear-specific results.
2. Click on the Aided button.
3. Click on the Binaural button if the test is done in the Free Field so that the results are stored for both ears at the same time.
4. Proceed with test; results will then be stored as aided by showing an Aided icon.

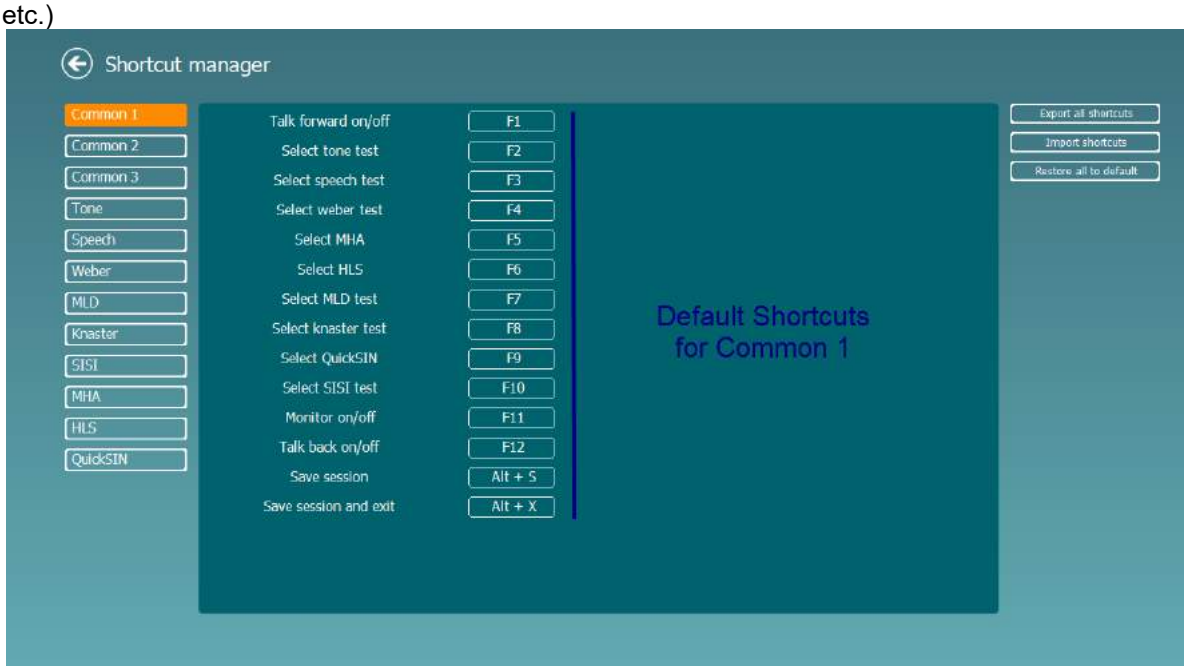


3.2.3 PC keyboard shortcuts manager

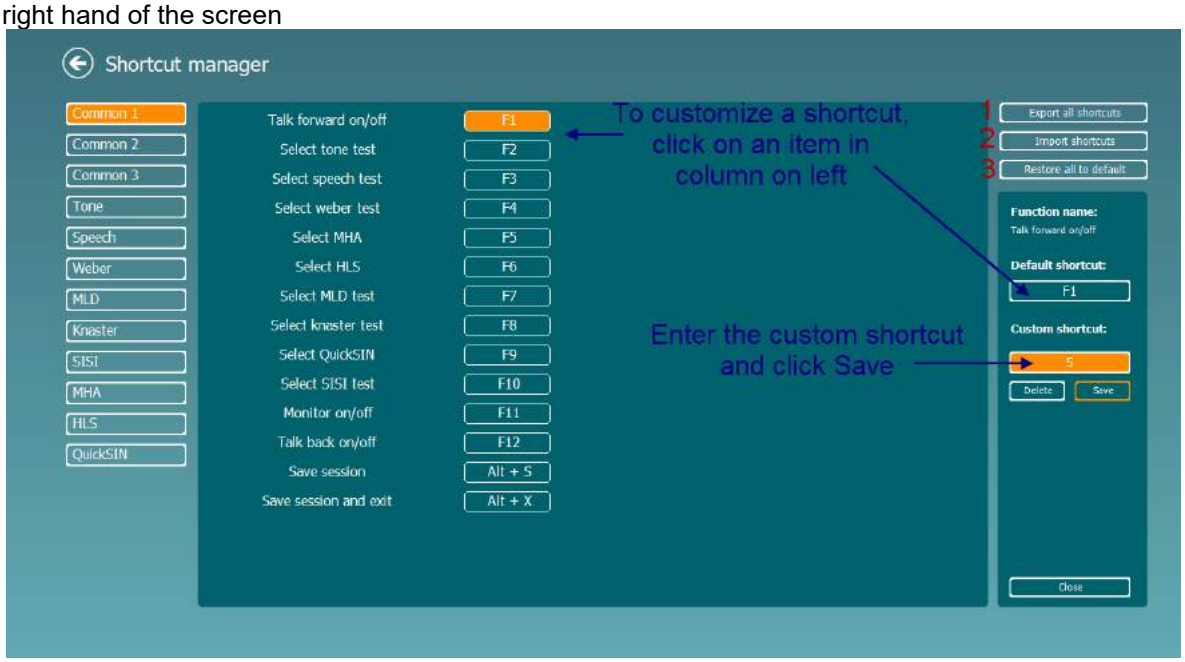
The PC Shortcut Manager allows the user to personalize PC shortcuts in the AC440 Module. To access the PC Shortcut Manager:

Go to AUD module │Menu │ Setup │PC Shortcut Keys

To view the default shortcuts, click on the items in the left hand column (Common 1, Common 2, Common 3, etc.)



To personalize a shortcut, click on the column in the middle and add the custom shortcut in the field on the right hand of the screen



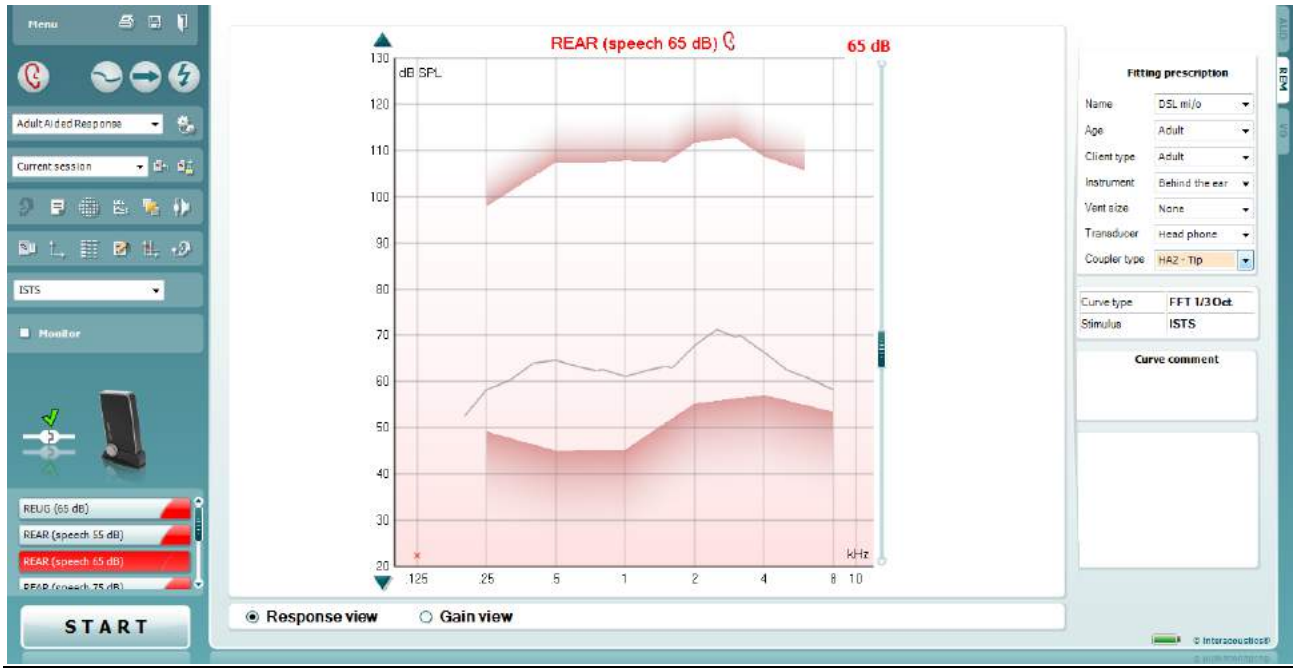
1. **Export all shortcuts**: Use this function to save custom shortcuts and transfer them to another computer
2. **Import shortcuts**: Use this function to import shortcuts that have already been exported from another computer
3. **Restore all defaults**: Use this function to restore the PC shortcuts to Factory Settings default

3.2.4 Technical specifications of the AC440 software

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Audiometer Standards:	Tone: IEC60645-1/ANSI S3.6 Type 1 Speech: IEC60645-2/ANSI S3.6 Type A or A-E	
Transducers & Calibration:	Calibration information and instructions are located in the Service manual. Check the accompanying Appendix for RETSPL levels for transducers	
Air Conduction		
DD45	ISO 389-1 2017, ANSI S3.6-2018 ±0.5N	Headband Static Force 4.5N
TDH39	ISO 389-1 2017, ANSI S3.6-2018 ±0.5N	Headband Static Force 4.5N
HDA300	ISO 389-8 2006, ANSI S3.6-2010 ±0.5N	Headband Static Force 8,8N
DD450	ANSI S3.6-2018 ±0.5N	Headband Static Force 10N
HDA280	PTB report 2004 ±0.5N	Headband Static Force 5N
E.A.R Tone 3A/5A	ISO 389-2 1998, ANSI S3.6-2010	
IP30	ISO 389-2 1998, ANSI S3.6-2018	
CIR 33	ISO 389-2	
Bone Conduction	Placemenet: Mastoid	
B71	ISO 389-3 2016, ANSI S3.6-2010 ±0.5N	Headband Static Force 5.4N
B81	ISO 389-3 2016, ANSI S3.6-2010 ±0.5N	Headband Static Force 5.4N
Free Field	ISO 389-7 2005, ANSI S3.6-2010	
High Freqency	ISO 389-5 2004, ANSI S3.6-2010	
Effective masking	ISO 389-4 1994, ANSI S3.6-2010	
Patient Response switch:	Hand held push button.	
Patient communication:	Talk Forward and Talk Back.	
Monitor:	Output through external earphone or speaker.	
Stimuli:	Pure tone, Wable tone,NB, SN, WN, TEN noise	
Tone	125-16000Hz separated in two ranges 125-8000Hz and 8000-16000Hz. Resolution 1/2-1/24 octave.	
Warble Tone	1-10 Hz sine +/- 5% modulation	
Wave file	44100Hz sampling, 16 bits, 2 channels	
Masking	Automatic selection of narrow band noise (or white noise) for tone presentation and speech noise for speech presentation.	
Narrow band noise:	IEC 60645-1:2001, 5/12 Octave filter with the same centre frequency resolution as pure Tone.	
White noise:	80-16000Hz measured with constant bandwidth	
Speech Noise.	IEC 60645-2 1993 & ANSI S3.6 2010: 125-6000Hz falling 12dB/octave above 1KHz +/-5dB	
Presentation	Manual or Reverse. Single or multiple pulses. pulse time adjustable from 200ms-5000ms in 50mS steps. Simultaneous or alternating.	
Intensity	Check the accompanying Appendix for maximum output levels	
Steps	Available Intensity Steps is 1, 2 and 5dB	
Accuracy	Sound pressure levels: ± 2 dB. Vibration force levels: ± 5 dB.	

Extended range function	If not activated, the Air Conduction output will be limited to 20 dB below maximum output.
Frequency	Range: 125Hz to 8kHz (Optional High Freqency: 8 kHz to 16 kHz) Accuracy: Better than ± 1 %
Distortion (THD)	Sound pressure levels: below 1.5 % Vibration force levels: below 3 %.
Signal Indicator(VU)	Time weighting: 350mS Dynamic range: -20dB to +3dB Rectifier characteristics: RMS Selectable inputs are provide with an attenuator by which the level can be adjusted to the indicator reference position(0dB)
Storing capability:	Tone audiogram: dB HL, MCL, UCL, Tinnitus, R+L Speech Audiogram: WR1, WR2, WR3, MCL, UCL, Aided, Unaided, Binaural, R+L.
Compatible Software:	Noah 4, OtoAccess® and XML compatible

3.3 REM440 screen elements





Menu provides access to File, Print, Edit, View, Mode, Setup, Help



Print button allows you to will print the test results currently displayed on the screen.



Save & New session button saves the current session in Noah or OtoAccess® and opens a new one.



Save & Exit button saves the current session in Noah or OtoAccess® and exits the Suite.



Change Ear button allows you to toggle between right and left ear. Right click on the ear icon to view both measurements on the same graph

Right click



NOTE: Binaural REM measurements can be performed when both ears are viewed (in both REIG measures and REAR). The binaural feature enables the fitter to view the binaural right and left measurements simultaneously.



Toggle between Single and Combined Screen button toggles between viewing one or multiple measurements in the same REM graph.



Toggle between Single and Continuous Measurement button toggles between running a single sweep and having a test signal running continuously until pressing STOP.



Freeze Curve button allows for taking a snapshot of a REM curve when testing with broadband signals. In other words the curve freezes at a particular moment while the test continues. **NOTE:** The Freeze Curve option only works for broadband (ex: ISTS) signals in the continuous mode.

Note that if too many curves are frozen on the screen not all will be saved in Noah due to imposed limitations.



List of Protocols allows you to select a test protocol (default or user defined) to use in the current test session.



Temporary Setup button allows for making temporary changes to the selected test protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the test protocol will be followed by an asterisk (*).



List of Historical Sessions accesses historical sessions for comparison or printing purposes.



Toggle between Lock and Unlock the Selected Session freezes the current or historical session on the screen for comparison to other sessions.



Go to Current Session button brings you back to current session.



Toggle between Coupler and Ear button allows you to toggle between real-ear and coupler/test box mode.

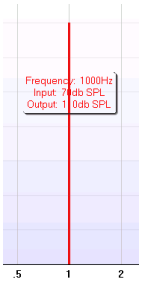
NOTE: This icon only becomes active if a RECD (measured or predicted) is available.



Report Editor button opens a separate window for adding notes to the current session. After saving the session, changes can only be made within the same day until the date changes (at midnight). **Note:** these timeframes are limited by HIMSA and the Noah software, and not by Interacoustics.



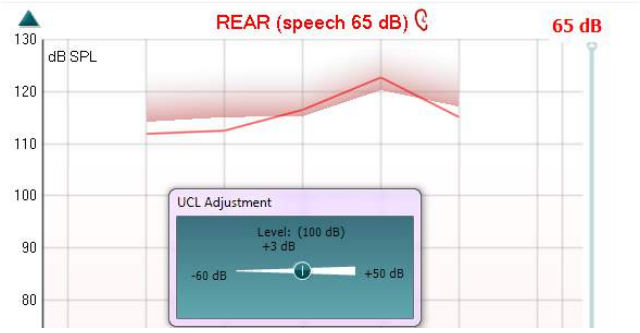
Single Frequency button is a test that lets the fitter play a single frequency warble tone. Once clicked, the exact frequency, input and output can be seen on the graph. The frequency can be adjusted up and down by using the Right and Left arrows on the keyboard. Click on the button to turn it on, and click on it again to turn it off.





UCL (Uncomfortable Levels) Adjustment
To limit the system's signal intensity while measuring the MPO during a Real-Ear situation, the UCL button can be activated. Once activated, a red line will appear on the graph and the system will stop measuring if this UCL level is reached. This red line can be adjusted with the slider.

NOTE: UCL thresholds must be entered on the audiogram for the red line to appear when the UCL button is active. To deactivate this feature, press on the UCL button again.





On Top Mode button converts the REM440 into an on top window that includes only the most essential REM features. The window is automatically placed on top of other active software programs such as the relevant hearing aid fitting software.
Whilst adjusting the gain handles in the fitting software, the REM440 screen will at all times stay on top of the fitting screen allowing for easy curve comparison.

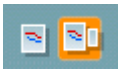


To return to the original REM440 press the red cross in the upper right hand corner .



Tube calibration button activates the tube calibration. Before measuring it is recommended to calibrate the probe tube. This is done by pressing the calibration button. Follow the instructions appearing on the screen (see screen below) and press OK. The calibration will then automatically be performed resulting in the curve below. Note that the calibration is sensitive to noise and the clinician should therefore ensure that the room is quite while calibrating.





Simple View/Advanced View buttons toggle between an advanced screen view (including the test and fitting prescription information on the right hand side) and a more simple view with a larger graph only.





Normal and Reversed Coordinate System buttons enable you to toggle between reversed and normal graph displays.
This may be helpful for counselling purposes since the reversed view look more similar to the audiogram and may therefore be easier for the client to comprehend when explaining his/her results.



Insert/Edit Target button allows you to type in an individual target or edit an existing one. Press the button and insert the preferred target values in the table as illustrated below. When satisfied click OK.

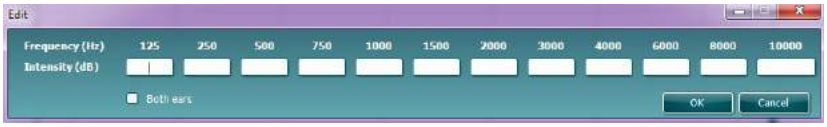
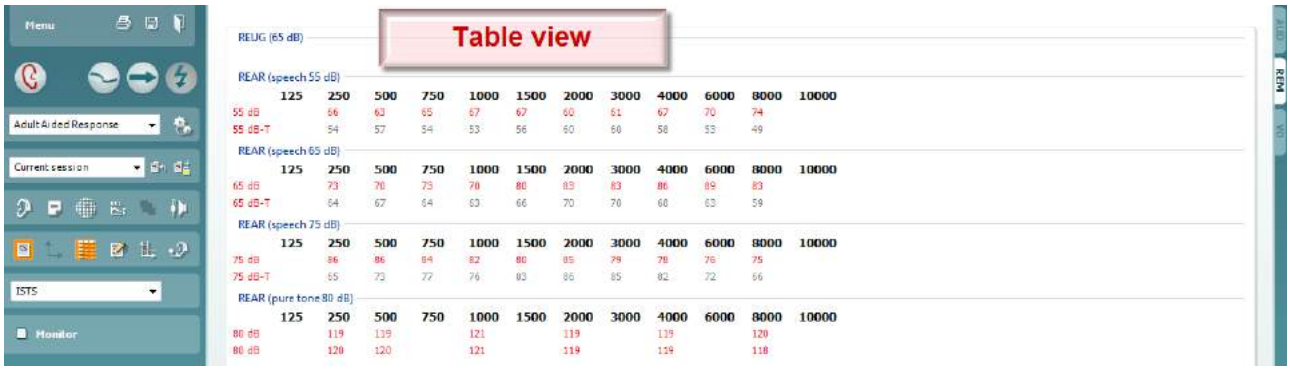


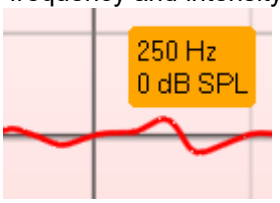


Table View button provides a chart view of the measured and target values.





Show Cursor on Graph locks the cursor to the curve, displaying the frequency and intensity at any given point along the measure curve.





Use Opposite Reference Microphone lets the fitter use a reference microphone is on the opposite to the ear in which the probe measurement microphone is. To use this feature, position the probe tube in the patient's ear, with the hearing aid in. Position the other reference microphone on the other patient's ear. By pressing on this button, the reference mic on the opposite side is the one be used during the measurement. This type of scenario is often used in CROS and BiCROS fittings.



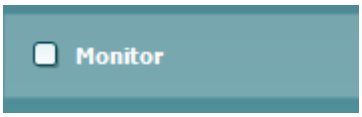
Single Graph lets the fitter view the binaural mesurement in one graph, overlaying the curves from the left and the right ear on top of one another.



Enable/disable delta values lets the fitter to see the calculated difference between the measurement curve and the target.



Stimulus Selection: With this dropdown list the test stimulus can be chosen.



Monitor: If you wish to listen to the amplified stimulus through a monitor.

1. Connect a monitor headset to the monitor output on the hardware. It is recommended to use only a monitor headset which is approved by Interacoustics.
2. Tick the Monitor check box.
3. Use the slider to turn the sound level up and down.



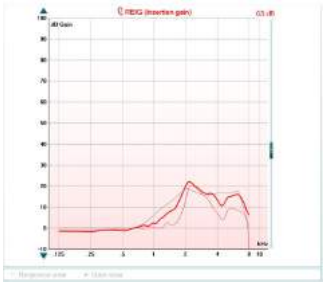
Note that the sound from the monitor may be very soft (compared to the audiometry monitoring). It is louder for audiometry because the audiometric equipment is producing the signal that is monitored. In REM440 the hearing instrument produces the monitored signal meaning that it cannot be controlled by the equipment.



Current Protocol is listed in the lower left hand corner.
Upon performing a test the system automatically jumps to the next one in the test flow. A checkmark indicates that a curve has been measured.
Test protocols can be created and adjusted in the REM440 setup.
The **colour** on each test button (in this case blue) indicates the colour selected for each curve.



START/STOP button initiates and ends the current test. Note that after pressing START the text on the button will change to STOP.



The Graph shows measured REM curves. The X axis shows the frequency and the Y axis shows the intensity of the test signal.
Gain/Response View allows for toggling between viewing the curve as a gain or response curve. Note that this option is not active for REIG .
Measurement Type is indicated above the graph together with a right/left indication. In this example the REIG is displayed for the right ear.
Change the Input Level using the slider on the right hand side.
Scroll Graph Up/Down on the left hand side allows for scrolling the graph up or down ensuring that the curve is always visible in the middle of the screen.



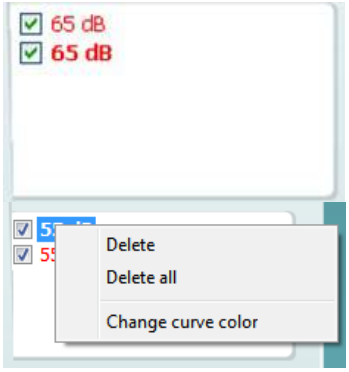
Fitting Prescription and related details can be adjusted on the right hand side of the screen. Select your preferred fitting prescription in the upper dropdown list.
Choose between Berger, DSL *m*[i/o], Half Gain, NAL-NL1, NAL-NL2, NAL-R, NAL-RP, POGO1, POGO2, Third Gain, or 'Custom' if you have edited your target with the *Edit/Insert target* feature.
Targets shown will be calculated based on the selected fitting prescription and the audiogram and can be shown in the REIG and/or REAR targets. **If no audiogram has been entered into the audiogram screen, no targets will be displayed.**
Note that fitting prescription settings (such as *Age* and *Client type*) will differ depending on what fitting prescription is selected.



Measurement Details of the selected curve are displayed as a table on the right hand side of the screen.

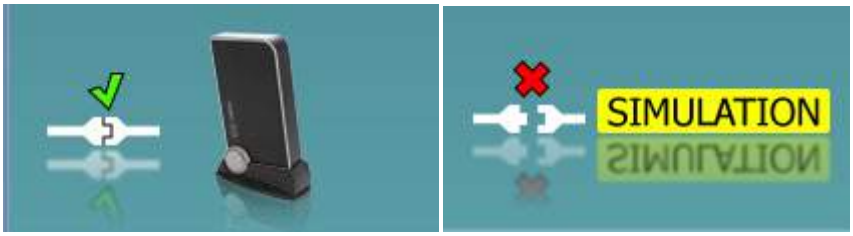


A Curve Comment for each curve can be typed into the comment section on the right hand side.
Select a curve using the curve tag boxes under Curve display options and write a comment in the comment section.
The comment will then appear in the comment section whenever the curve is selected.



Curve Display Options are found in the lower right hand corner.
If you have measured more curves of the same type (e.g. REIG curves), they will be listed by their input level. Tick the ones that are to be displayed on the graph.

Right clicking on the input level in the curve display will give the fitter various options



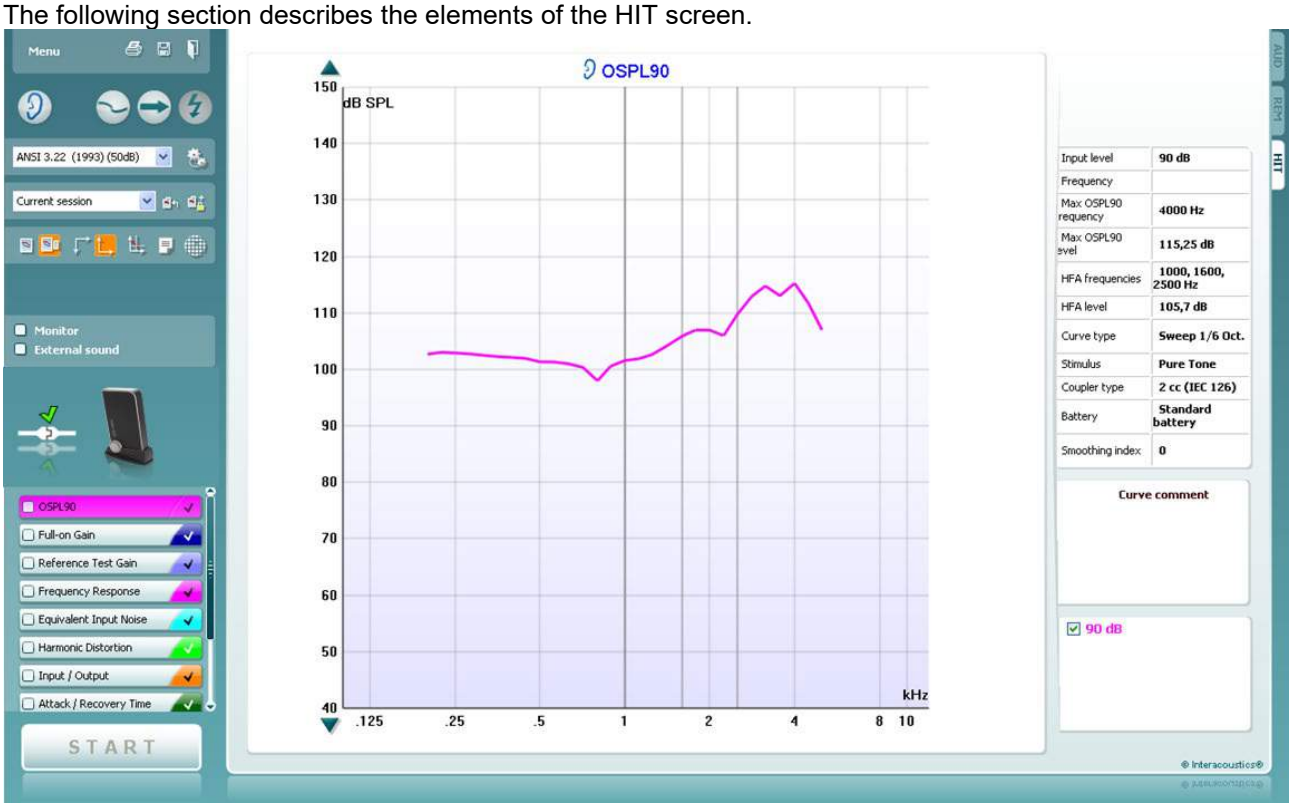
Hardware indication picture: The picture indicates whether the hardware is connected.
When opening the Suite the system will search for the hardware. If it does not detect the hardware then the system will automatically continue in simulation mode and the Simulation icon (above right) will show in place of the connected hardware indication picture (above left).

3.3.1 REM440 software - technical specifications

Medical CE-mark:		The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Real Ear Measurement Standards:		IEC 61669, ISO 12124, ANSI S3.46.	
Stimuli:		Warble Tone, Pure Tone, Random noise, Pseudo random noise, Band limited white noise, Chirp, ICRA, Real Speech, any other sound file (automatic calibration available).	
	Frequency range:	100Hz – 10kHz	
	Frequency accuracy:	Less than ± 1 %	
	Distortion:	Less than 2%	
	Intensity range:	40 – 90 dB	
	Intensity accuracy:	Less than ± 1.5 %	
Measurement Intensity Range:		Probe microphone 40-140 dB SPL ± 2 dB.	
Frequency Resolution:		1/3, 1/6, 1/12, 1/24 octave or 1024 point FFT.	
Probe microphone:		Intensity: 40 – 140 dB	
Reference microphone:		Intensity: 40 – 100 dB	
Intensity Accuracy:		Less than ± 1.5 dB	
Cross talk		Cross talk in the probe and probe tube will alter the obtained results with less than 1 dB at all frequencies.	
Available tests:		REUR REIG RECD REAR REAG REOR	REOG REUG Input – Output FM Transparency Directionality Visible speech mapping
Compatible Software:		Noah 4, OtoAccess® and XML compatible	

3.4 The HIT440 screen

The following section describes the elements of the HIT screen.





Menu provides access to Print, Edit, View, Mode, Setup, and Help.



Print button allows you to print only the test results currently displayed on the screen. To print multiple tests on one page, select Print then Print Layout



Save & New Session button saves the current session in Noah or OtoAccess® and opens a new one.



Save & Exit button saves the current session in Noah or OtoAccess® and exits the Suite.



Change Ear button allows you to toggle between right and left ear. Right click on the ear icon to view *both ears*.



Toggle between single and combined screen button toggles between viewing one or multiple measurements in the same HIT graph.



Toggle between single and continuous measurement button toggles between running a single sweep or having a test signal running continuously until pressing STOP.



Freeze curve allows for taking a snapshot of a HIT curve when testing with broadband signals. In other words the curve freezes at a particular moment while the test continues.

NOTE: The Freeze Curve option onlyl works in a enduser-created protocol, for broadband (ex: ISTS) signals in the continuous mode.



List of Protocols allows you to select a test protocol (default or user defined) to use in the current test session.



Temporary Setup button allows for making temporary changes to the selected test protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the test protocol will be followed by an asterisk (*).
NOTE: Protocols from ANSI and IEC cannot be temporarily modified.



List of historical sessions accesses historical sessions for comparison purposes.



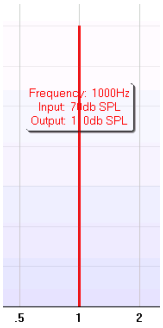
Toggle between Lock and Unlock the Selected Session freezes the current or historical session on the screen for comparison to other sessions.
Go to Current Session button brings you back to current session.



Report Editor button opens a separate window for adding notes to the current session. Note that after saving the session no changes can added to the report.



Single frequency button represents an optional manual test that allows for presetting hearing aid gain prior to HIT.
Place the hearing aid in the ear test box and press the single frequency button. A 1000 Hz tone will then appear allowing you to see the exact input and output of the hearing aid. Press the button again to end the test.





Simple view/Advanced view buttons toggle between an advanced screen view (including the test and fitting prescription information on the right hand side) and a more simple view with a larger graph.

Advanced view



Simple view

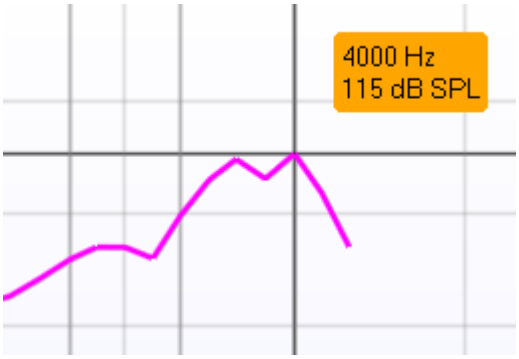




Normal and reversed coordinate system buttons enable you to toggle between reversed and normal graph.



Show curser on graph provides information about each specific measured point in the curve. The curser is “locked” to the curve and a frequency and intensity label will be displayed at the curser’s position, as illustrated below:





Stimulus Selection allows for selecting a test stimulus. The dropdown is only present for custom made test protocols. The standards (e.g. ANSI and IEC) have fixed stimuli.



Monitor: If you wish to listen to the amplified stimulus through a monitor.

1. Connect a monitor speaker the monitor output on the hardware.
2. Tick the Monitor check box.
3. Use the slider to turn the sound level up and down.

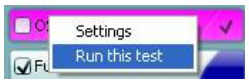
Note that the sound from the monitor may be very soft (compared to the audiometry monitoring). It is louder for audiometry because the audiometric equipment is producing the signal that is monitored. In HIT440 the hearing instrument produces the monitored signal meaning that it cannot be controlled by the equipment. However, if you have an active speaker it will be louder.

External sound: You can present an external sound through for example a CD player if you have a piece of music/speech you wish to use. This may have a strong effect for counselling purposes.

1. Connect the CD player to the CD1 input on the hardware.
2. Press START in the software and then tick the External sound check box. The external sound will then play together with the signal.
3. Use the slider to turn the sound level up and down.



Current Protocol is listed in the lower left hand corner. The ☑ indicates the test is a part of an automatic test flow (Auto Run). When pressing START all tests with the tick mark will be performed.

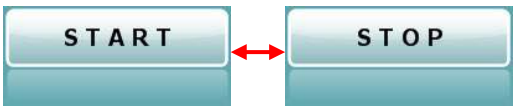


If you wish to perform one test only, mark it using the mouse by clicking on it. Then right click at select *Run this test*.

Upon performing a test the system automatically jumps to the next one in the test flow. ☑ indicates that a curve has been measured.

Colour indication shows the colour selected for each curve.

Test protocols can be created and adjusted in the HIT440 Setup.



Start/Stop button initiates and ends all tests.
Note that after pressing *START* the text on the button will change to *STOP*.



The Graph shows measured HIT curves. The X axis shows the frequency and the Y axis shows ouput or gain, depending on which measurement was done.

Measurement type is printed above the graph together with a right/left indication. In this example the OSPL90 is displayed for the left ear.

Change the input level using the slider on the right hand side.
NOTE: for the industry standard protocols (ANSI and IEC), the input level is dictated by the standard and cannot be changed.

Scroll graph up/down on the left hand side allows for scrolling the graph up or down ensuring that the curve is always visible in the middle of the screen.

Input level	**90 dB**
Frequency	
Max OSPL90 requency	**4000 Hz**
Max OSPL90 evel	**115,25 dB**
HFA frequencies	**1000, 1600, 2500 Hz**
HFA level	**105,7 dB**
Curve type	**Sweep 1/6 Oct.**
Stimulus	**Pure Tone**
Coupler type	**2 cc (IEC 126)**
Battery	**Standard battery**
Smoothing index	**0**

Measurement details: In this table the curve details can always be viewed. This way the professional always has an overview of what is being measured. Read information such as Input Level, Max SPL, Curve Type, Stimulus, and Curve type.



A Curve Comment for each curve can be typed into the comment section on the right hand side. Select a curve using the curve tag boxes under Curve display options and write a comment in the comment section.
The comment will then appear in the comment section whenever the curve is selected.

Curve Display Options are found in the lower right hand corner.
If you have measured more curves of the same type (e.g. Frequency response curves), they will be listed by their input level. Tick the ones that are to be displayed on the graph.

The hardware indication picture indicates whether the hardware is connected.

When opening the Suite the system will search for the hardware. If it does not detect the hardware then the system will automatically continue in simulation mode.

3.4.1 HIT440 software - technical specifications

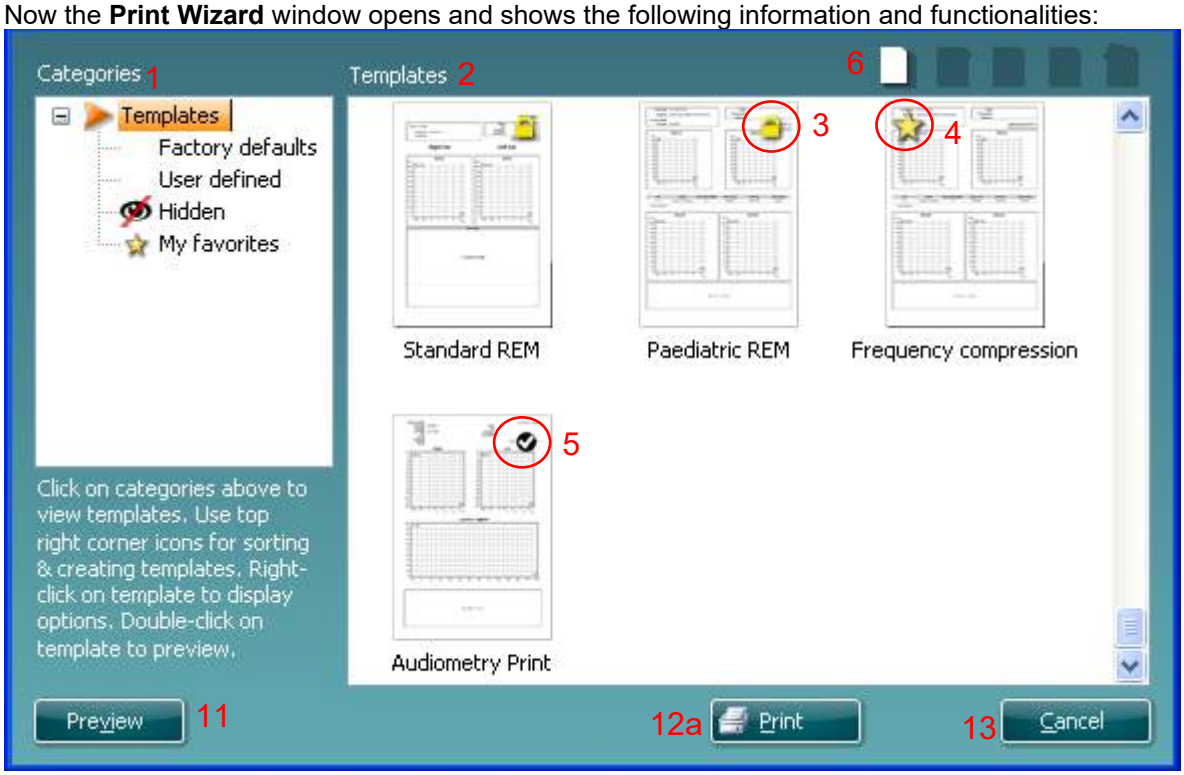
Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Hearing Aid Analyzer Standards:	IEC 60118-0, IEC 60118-7, ANSI S3.22.	
Frequency Range:	100-10000Hz.	
Frequency Resolution:	1/3, 1/6, 1/12 and 1/24 octave or 1024 point FFT.	
Frequency Accuracy:	Less than ± 1 %	
Stimulus Signal:	Warble Tone, Pure Tone, Random noise, Pseudo random noise, Band limited white noise, Chirp, ICRA, Real Speech, any other sound file (automatic calibration available).	
Sweep Speed:	1,5 – 80 sec.	
FFT:	Resolution 1024 points. Averaging: 10 – 500.	
Stimulation Intensity Range:	40-100 dB SPL in 1 dB step.	
Intensity Accuracy:	Less than ± 1.5 dB	
Measurement Intensity Range:	Probe microphone 40-145 dB SPL ± 2 dB.	
Stimulus Distortion:	Less than 1 % THD.	
Available tests:	Additional tests can be designed by user	
	OSPL90 Full On Gain Input/Output Attack/Recovery Time Reference Test Gain Frequency Response Equivalent Input Noise	Harmonic Distortion Intermodulation Distortion Microphone Directionality
Pre-Programmed Protocols:	HIT440 software comes with a set of Test Protocols loaded. Additional Test Protocols can be designed by user, or easily imported into the system.	
Compatible Software:	Noah 4, OtoAccess® and XML compatible	

3.5 Using the print wizard

In the Print Wizard you have the option to create customized print templates which can be linked to individual protocols for quick printing. The Print Wizard can be reached in two ways.

a. If you want to use a template for general use, or select an existing one for printing: Go to **Menu/ Print/Print layout…** Callisto™ Suite tabs (AUD or REM).
b. If you want to create a template or select an existing one to link to a specific protocol: Select the Module tab (AUD or REM) relating to the specific protocol and select **Menu/Setup/AC440 setup** or **Menu/Setup/REM440 setup**. Select the specific protocol from the drop down menu and select **Print Setup** at the bottom of the window.

Now the **Print Wizard** window opens and shows the following information and functionalities:



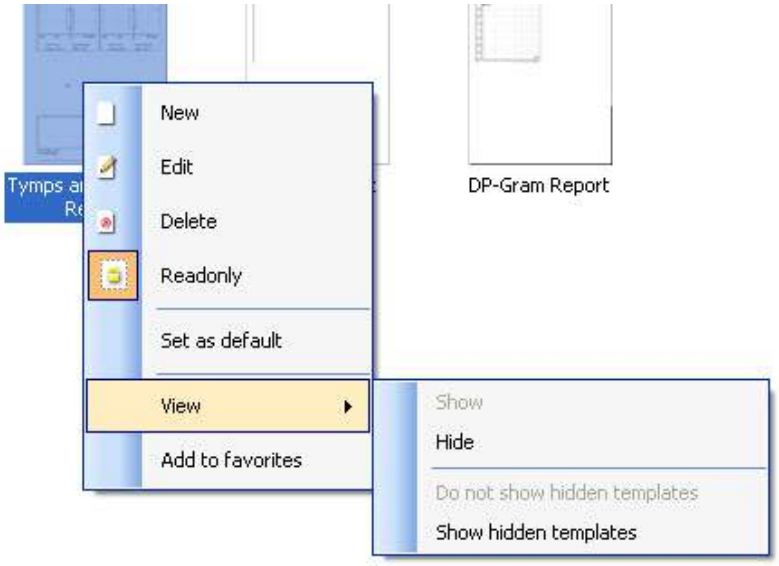
1. Underneath **Categories** you can select



   - **Templates** to show all available templates
   - **Factory defaults** to show only standard templates
   - **User defined** to show only custom templates
   - **Hidden** to show hidden templates
   - **My favorites** to show only templates marked as a favorite
2. Available templates from the selected category are shown in the **Templates** viewing area.
3. Factory default templates are recognized by the lock icon. They ensure that you always have a standard template and do not need to create a customized one. However, in order to edit these defaulut templates, they need to be saved under a new name. **User defined**/created templates can be set to **Read-only** (showing the lock icon), by right clicking on the template and selecting **Read-only** from the drop down list. **Read-only** status can also be removed from **User defined** templates by following the same steps.
4. Templates added to **My favorites** are marked with a star. Adding templates to **My favorites** allows quick viewing of your most commonly used templates.
5. The template that is attached to the selected protocol when entering the print wizard via the **AC440** or **REM440** window is recognized by a checkmark.
6. Press the **New Template** button to open a new empty template.

7. Select one of the existing templates and press the **Edit Template** button to modify the selected layout.
8. Select one of the existing templates and press the **Delete Template** button to delete the selected template. You will be prompted to confirm that you want to delete the template.
9. Select one of the existing templates and press the **Hide Template** button to hide the selected template. The template will now be visible only when **Hidden** is selected under **Categories**. To unhide the template, select **Hidden** under **Categories**, right click on the desired template and select **View**/**Show**.
10. Select one of the existing templates and press the **My Favorites** button to mark the template as a favorite. The template can now be quickly found when **My Favorites** is selected under **Categories**. To remove a template marked with a star from My Favorites, select the template and press the **My Favorites** button.
11. Select one of the templates and press the **Preview** button to print preview the template on screen.
12. Depending how you reached the Print Wizard, you will have the option to press
    a. **Print** for using the selected template for printing or press.
    b. **Select** for dedicating the selected template to the protocol from which you got into the Print Wizard.
13. To leave the Print Wizard without selecting or changing a template press **Cancel**.

Right clicking on a specific template provides a drop down menu offering an alternative method for performing the options as described above:



For more information related to the Print reports and Print Wizard, please refer to the Callisto Additional Information document or the Print Report Quick Guide on www.interacoustics.com



4. Maintenance

4.1 General maintenance procedures

The performance and safety of the instrument will be kept if the following recommendations for care and maintenance are observed:

- The instrument must go through at least one annual overhaul, to ensure that the acoustical, electrical and mechanical properties are correct. This should be made by an authorised workshop in order to guaranty proper service and repair as Interacoustics provides the necessary circuit diagrams etc. to these repair shops.
- To ensure that the reliability of the instrument is kept, it is recommended that the operator at short intervals, for instance once a day, perform a test on a person with known data. This person could be the operator him/herself.
- After each examination of a patient, it should be ensured that there is no contamination on the parts in connection with the patient. General precautions must be observed in order to avoid that disease from one patient is conducted to others. If ear cushions or ear tips are contaminated, it is strongly recommended to remove them from the transducer before they are cleaned. By frequent cleaning water should be used, but by severe contamination it may be necessary to use a disinfectant. The use of organic solvents and aromatic oils must be avoided.

4.2 How to clean Interacoustics products



- Before cleaning always switch off and disconnect from the power supply
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with the metal parts inside the earphones/headphones
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use components
- Ensure that isopropyl alcohol does not come into contact with any screens on the instruments
- Ensure that isopropyl alcohol does not come into contact with any silicone tubes or rubber parts

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- Normal hospital bactericides
- 70% isopropyl alcohol only on hard cover surfaces

Procedure

- Clean the instrument by wiping outer case with a lint free cloth lightly dampened in cleaning solution
- Clean cushions and patient hand switch and other parts with a lint free cloth lightly dampened in cleaning solution
- Make sure not to get moisture in the speaker portion of the earphones and similar parts

4.3 Concerning repair

Interacoustics is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

1. assembly operations, extensions, readjustments, modifications or repairs are carried out by authorised persons
2. a 1 year service interval is maintained
3. the electrical installation of the relevant room complies with the appropriate requirements, and
4. the equipment is used by authorised personnel in accordance with the documentation supplied by Interacoustics.

It is important that the customer (agent) fills out the RETURN REPORT every time a problem arises and sends it to **Interacoustics Inc.**
10393 West 70th Street
Prairie
MN 55344
USA

This should also be done every time an instrument is returned to Interacoustics. (This of course also applies in the unthinkable worst case of death or serious deterioration to patient or user).

4.4 Warranty

INTERACOUSTICS warrants that:

- The Callisto™ is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser.
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk.

In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative
- altered in any way so as, in Interacoustics judgement, to affect its stability or reliability
- subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

5. General technical specifications

Callisto™ general technical specifications

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no. 0123.	
Standards:	**Safety:**	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + A1:2012 ANSI/AAMI ES60601-1:2005 + A2:2010 2 A1:2012 CAN/CSA-C22.2 No. 60601-1:14 USB powered, Applied parts type B
	EMC:	IEC 60601-1-2:2014 (4. ed.)
	Audiometer Tone:	IEC 60645-1 2001/ANSI S3.6-2010 , Type 1 Tone audiometer IEC 60645-4 1994/ANSI S3.6-2010 , High frequency audiometer
	Audiometer Speech:	IEC 60645-2 1997/ANSI S3.6-2010 Type A or A-E, STAF-1996, Norway. Speech audiometer
	Audiometer Calibration:	AC: DD45 PTB/DTU report 2009 TDH39: ISO 389-1 1998, ANSI S3.6-2010 HDA200: ISO 389-5 2006, ANSI S3.6-2010 HDA300: PTB Report 1.61-4064893/13 2013 E.A.R Tone 3A/5A: ISO 389-2 1994, ANSI S3.6-2010 BC: B71: ISO 389-3 1994, ANSI S3.6-2010 FF: ISO 389-7 2005, ANSI S3.6-2010 HF: ISO 389-8 2004, ANSI S3.6-2010 Effective masking: ISO 389-4 1994, ANSI S3.6-2010
	Hearing Aid Analyzer:	IEC 60118-0 1983, IEC60118-1 1998, IEC 60118-7 2005, ANSI S3.22-2003.
	Real ear measurement:	IEC61669 2001, ISO12124 2001, ANSI S3.46-1997
Specifications Callisto™ Hardware:		
PC requirements:		2 GHz Intel i3 processor 4GB Ram 2.5 GB available disk space 1024x768 resolution (1280x1024 or higher recommended) Hardware accelerated DirectX/Direct3D graphics card. One or more USB ports, version 1.1 or higher.
Supported Systems:		Windows® 7 (32 and 64 bit) Windows® 8 (64 bit) Windows® 10 (64 bit)
Available modules:		Callisto™ Suite AUD, REM, HIT.
Database:		OtoAccess® and Noah-compatible office systems or later releases
Computer Communication:		USB interface, compatible with USB1.1 or later.
Construction:		Plastic cabinet.
Power:		USB-powered with an internal “power boost” rechargeable battery and load balancer. Average: 300mA (Max: 500mA)
Battery : **Battery working voltage :** **Operation environment:**		NP120 3.7V 1700 mAH battery lithium ion 53x35.2x11. 3.2 to 4.2V

	Rel. Humidity: **Temperature:** **Ambient Pressure:**	15 – 90% 10-35° 98 kPa – 104 kPa
Transport temperature:		-20-50 °C
Storage temperature:		0-50 °C
Humidity transportation & storage:		10% to 95% RH. Non condensing
Dimensions:		212 x 121 x 44 mm / 8.3 x 4.8 x 1.7 inches
Weight:		**5.25 bs (822g / 1.81 lbs with cradle)**

5.1 Reference equivalent threshold values for transducers and maximum hearing level settings provided at each test frequency

See Appendix A in English in the back of the manual.

5.2 Pin assignments

See Appendix B in English in the back of the manual.

5.3 Electromagnetic Compatibility (EMC)

See Appendix C in English in the back of the manual.

Return Report – Form 001

Interacoustics

Opr. dato:	af:	Rev. dato:	af:	Rev. nr.:	
2014-03-07	EC		MSt	4	

Company: _____

Address: _____

_____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone
(+1) 800 947 6334

Fax
(+1) 952 903 4200

E-mail
rmd@interacoustics-us.com

Contact person: _____ Date: _____

Following item is reported to be:

☐ returned to INTERACOUSTICS for: ☐ repair, ☐ exchange, ☐ other: _____

☐ defective as described below with request of assistance

☐ repaired locally as described below

☐ showing general problems as described below

Item: Type: _____ Quantity: _____

Serial No.: _____ Supplied by: _____

Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

_____

_____

_____

Returned according to agreement with: ☐ Interacoustics, ☐ Other : _____

Date : _____ Person : _____

Please provide e-mail address or fax No. to whom Interacoustics may confirm reception of the returned goods: _____

☐ **The above mentioned item is reported to be dangerous to patient or user** [1]

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

[1] EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user.